THE PREDICTIVE POWER OF PATENTS

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Abstract

This article explains that domestic patenting activity may foreshadow a country's level of regulation of path-breaking technologies. The article considers whether different governments will act with a light or a heavy regulatory hand when encountering a new disruptive technology. The article hypothesizes that part of the answer to this important regulatory, economic, and geopolitical question may lie in an unexpected place: the world's patent offices. Countries with early and significant patent activity in an emerging technology are more likely to view themselves as having a stake in the technology and therefore will be less inclined to subject the technology to extensive health, safety and environmental regulation that would constrain it. The article introduces the term "patent footprint" to describe a country's degree of patenting activity in a new technology, and the article posits that a country's patent footprint may provide an early clue to its willingness or reluctance to strenuously regulate the new technology. Even more so, lack of geographic diversity in patent footprints may help predict whether an emerging technology will face extensive international regulation. Patent footprints provide a useful tool to policymakers, businesses, investors, and NGOs considering the health, safety, and environmental regulation of a disruptive technology. The predictive power of patent footprints adds to the literature on the broader function of patents in society.

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I. INTRODUCTION

Patents, as classically construed, incentivize innovation by giving inventors exclusive rights to their discoveries.[1] Over the years, scholars have shown that patents serve purposes other than the assignment of ownership to important technological advances. Patents, even if never licensed, used, or enforced,[2] send important signals to the outside world.[3] They convey to potential investors information about firm productivity, innovative dynamism, and knowledge capital.[4] They provide a window into a firm's overall managerial competence and foresight.[5] They spotlight those working in a given area and may facilitate research and business collaborations,[6] as well as help investors and researchers ascertain the frontier of a given field.[7] They provide employers

1. U.S. CONST. art. I § 8, cl. 8.

2. *See* Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 5 (2005) (explaining the overwhelming majority of patents have a low average expected value); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L. J. 1521, 1522 (2005) (showing that average value of patents are less than their average acquisition costs); Mark Schankerman, *How Valuable is Patents Protection? Estimates by Technology Field*, 29 RAND J. ECON. 77, 93 (1998) ("most patents have very little private value").

3. Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 643–64 (2002). *See generally* Jay Kesan, *Economic Rationales for the Patent System in Current Context*, 22 GEO. MASON L. REV. 897, 911 (2015).

4. Long, *supra* note 3 at 651–52.

5. Stuart J. H. Graham et. al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L. J. 1255, 1306 (2009); *see* Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent*? 23 BERKELEY TECH. L.J. 1063, 1078 (2008) ("[E]ven if the patents cannot increase a company's profitability, they may signal to outsiders that the company is engaging in the sorts of practices that successful companies generally conduct"); *id*. at 637.

6. Daniel F. Spulber, *How Patents Provide the Foundation for the Market for Inventions*, 11 J. COMP. L. & ECON. 271, 310 (2015); Andrew Beckerman-Rodau et. al., *eBay v. MercExchange and Quanta Computer v. LG Electronics*, 4 J. BUS. & TECH. L. 5, 14 (2009) (quoting Kieff on how patents act as a beacon that draw people who share an interest in a given technology together); Julien Penin, *Patents Versus Ex Post Rewards: A New Look*, 34 RES. POL'Y 641, 642 (2005).

7. Jay Kesan, *Intellectual Property Protection and Agricultural Biotechnology: A Multidisciplinary Perspective*, 44 AM. BEHAV. SCIENTIST 464, 489 (2009); Long, *supra* note 3, at 648.

with information on employee productivity.[8] Even when economically worthless, they bestow prestige on inventors, signaling a life of accomplishment.[9]

This article theorizes that patents can telegraph something more dramatic and unexpected. Patents may signal early on whether a new technology will face extensive or modest health, safety, and environmental regulation, particularly at the international level. Confronted with a powerful new technology, governments must decide whether and to what extent to regulate it. The dangers of a new technology are often hypothetical, and the fog of ambiguity creates space for regulatory discretion. The extent and manner of regulation may determine whether a new technology will flourish or be constrained. The extent to which a country perceives itself to have a future in a new technology will affect its decision on how to regulate the technology. This article theorizes that a country's "patent footprint" in a new technology provides an early indicator of that future.

This article introduces the term "patent footprint" to connote the extent and intensity of a country's patent activity in a given technology as measured by the amount and quality of patents issued to a country's domestic inventors (including foreign patent offices) and, at times, by patent assignees from that country. To be clear, a country's patent footprint does not refer to the overall number of patents for a technology granted by a country's patent office (which would include patents granted to foreign inventors).

Whether a country will play an important role in a new technology often may be first gleaned in the patent office. Patent law serves as the legal system's sentinel at the frontier of technology.[10] It usually marks a watershed technology's first brush with the law. For example, long before government officials grappled with the regulation of biotechnology,[11] patent officials wrestled with whether to patent bioengineered organisms.[12] Similarly, inventors filed the earliest of nanotechnology patents in 1975,[13] while governments only

8. Richard Levin, *A New Look at the Patent System*, 76 AM. ECON. REV. 199, 200-01 (1986); Wesley M. Cohen et. al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (Nat'l Bureau of Econ. Rsch., Working Paper No. 752, 2000).

9. *See, e.g.*, 35 U.S.C. § 287(c) (2018) (permitting patents on methods of medical treatments while depriving patent holders of the right to enforce such patents against medical practitioners).

10. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003) ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.").

11. *See* Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Federal Register 23302 (June 26, 1986) [hereinafter *Coordinated Framework*]; Commission of the European Communities, *A Community Framework for the Regulation of Biotechnology* (Nov. 4, 1986) described in MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 60 (Oxford Univ. Press 2009).

12. While the first patent application for a bioengineered organism was filed in 1972 and the U.S. Supreme Court resolved the patent eligibility of bioengineered organisms by 1980, not until 1986 did either the United States or the European Communities regulate the technology. Diamond v. Chakrabarty, 447 U.S. 303, 303 (1980). The famous Cohen-Beyer biotechnology patent, which ultimately generated some $250 million to Stanford University was issued in 1980 and filed in year 1972. *See* U.S Patent No. 4,259,444 ("Microorganisms having multiple compatible degradative energy-generating plasmids and preparation thereof.").

13. Jordan Paradise, *Claiming Nanotechnology: Improving USPTO Efforts at Classification of Emerging Nano-Enabled Pharmaceutical Technologies*, 10 NW J. OF TECH. & INTELL. PROP. 169, 183 (2012) (The first

began to consider regulation of the field in the early 2000s.[14] That patent law acts as a legal sentinel comes as no surprise. The patent system purposefully encourages inventors to rush to the patent office as early as possible, lest another inventor obtain a patent on the invention first.[15] This promotes early disclosure of an invention, a prime objective of all patent systems.[16]

Scholars,[17] non-governmental organizations,[18] and government officials[19] have recently grappled with the regulatory future of nanotechnology. This powerful technology enables the building of matter from the atomic level up.[20] Nanotechnology even holds promise in the war against COVID-19. Tiny sponges made of nanoparticles, when inserted into the body, may block the

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nanotech patent within the USPTO patent classification system was filed in September 1975 and issued in August 1978. Injectable Compositions, Nanoparticles Useful Therein, & Process of Mfg. Same, U.S. Patent No. 4,107,288 (filed Sept. 9, 1975); Tyson Winarsk, et. al., *Nanotechnology Thriving on Patents*, INTELL. PROP. TODAY (Apr. 2005), at 26 (citing the National Science Foundation) (noting an earlier nanotech patent issued in 1976).

14. *E.g.*, EUROPEAN COMM'N CMTY. HEALTH & CONSUMER PROT., *Nanotechnologies: A Preliminary Risk Analysis on The Basis of a Workshop Organized in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission* 13 (2004), available at http://ec.europa.eu/health/ph_risk/documents/ev_20040301_en.pdf; OFFICE OF THE SCIENCE ADVISOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA 100/B–07/001, NANOTECHNOLOGY WHITE PAPER (2007).

15. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc. 489 U.S. 141, 141 (1989); Egbert v. Lippmann, 104 U.S. 333, 333 (1881).

16. *Id.*

17. *E.g.*, David B. Resnik, *How Should Engineered Nanomaterials Be Regulated for Public and Environmental Health*, AMA J. OF ETHICS, 363 (April 2019); Vincent R. Johnson, *Nanotechnology, Environmental Risks, and Regulatory Options*, 121 PENN ST. L. REV. 471 (2016); Dorothea K. Thompson, *Small Size, Big Dilemma: The Challenge of Regulating Nanotechnology*, 79 TENN. L. REV. 621 (2012); Daniel J. Fiorino, Woodrow Wilson International Center for Scholars, VOLUNTARY INITIATIVES, REGULATION, AND NANOTECHNOLOGY OVERSIGHT: CHARTING A PATH (2010); Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323 (2008); David B. Fischer, *Nanotechnology—Scientific and Regulatory Challenges*, 19 VILL. ENVTL. L.J. 315, 330 (2008); Jordan Paradise, et. al., *Developing Oversight Frameworks for Nanobiotechnology*, 9 MINN. J. OF L., SCI. AND TECH. 399 (2008); Robert Lee & P.D. Jose, *Self-interest, Self-restraint and Corporate Responsibility for Nanotechnologies: Emerging Dilemmas for Modern Managers*, 20 TECH. ANALYSIS & STRATEGIC MGMT. 113 (2008); J. CLARENCE DAVIES, EPA AND NANOTECHNOLOGY: OVERSIGHT FOR THE 21ST CENTURY 13, WOODROW WILSON INT'L. CENTER FOR SCHOLARS, (2007), https://core.ac.uk/download/pdf/11818756.pdf; Lee Paddock, *Keeping Pace with Nanotechnology: A Proposal for a New Approach to Environmental Accountability*, 3t ENVT'L L. REP. 10943 (2006); Andrew D. Maynard, *Safe Handling of Nanotechnology*, 44 NATURE 267, 267 (2006); INT'L RISK GOVERNANCE COUNCIL, SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME A. THE ROLE OF GOVERNMENT (2005); Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179, 182 (2003); Paul C. Lin-Easton, *It's Time for Environmentalist to Think Small – Real Small: A Call for the Involvement of Environmental Lawyers in Developing Precautionary Policies for Molecular Nanotechnology*, 14 GEO. INT'L ENVTL. L. REV. 107 (2001).

18. *E.g.*, ENVL. LAW INST., GOVERNING UNCERTAINTY: THE NANOTECHNOLOGY ENVIRONMENTAL, HEALTH, AND SAFETY CHALLENGE (2005); FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS BIG RISKS (2006); News Release, ETC Group, Nanotech Meets the Environment (Oct. 23, 2003), https://www.etcgroup.org/content/nanotech-meets-environment) (calling for a moratorium on the sale of nanotechnology personal health products).

19. *E.g.*, Nat'l Nanotechnology Initiative, Office of the President, Health and Safety Research Strategy (2011), (The 2011 Strategy replaces NNI's 2008 strategy); John F. Sargent Jr., Cong. Research Serv., RL 34401, THE NATIONAL NANOTECHNOLOGY INITIATIVE: OVERVIEW, REAUTHORIZATION, AND APPROPRIATIONS ISSUES 16 (2011); OFFICE OF THE SCI. ADVISOR, U.S. ENVTL. PROTEC. AGENCY, EPA 100/B–07/001, NANOTECHNOLOGY WHITE PAPER (2007). *See also*, Aida Maria Ponce Del Castillo, *The European and Member States' Approaches to Regulating Nanomaterials: Two Levels of Governance*, 7 NANOETHICS 189 (2013) (discussing nanotechnology regulation by different European governments).

20. MARK RATNER & DANIEL RATNER, NANOTECHNOLOGY: A GENTLE INTRODUCTION TO THE NEXT BIG IDEA, at 7 (2003) (contrasting to hewing and shaping matter at the macroscale as traditionally done).

deadly virus's spread but could unexpectedly damage the body in other ways.[21] Nanotechnology portends to revolutionize so vast an array of fields[22] that many see it as ushering in a second industrial revolution.[23] Like other transformative technologies before it, nanotechnology presents a vast array of uncertain health, safety, and environmental risks. Some call for robust oversight and even bans on nanotechnology.[24] Others call for a more flexible approach.[25] A key issue is whether, and to what extent, nanotechnology should fall subject to international regulation.[26]

In an earlier work, I showed how two of the most important transformative technologies of the past fifty years, biotechnology and the cellular telephone, faced diametrically different regulatory responses.[27] From the outset, biotechnology, particularly agricultural biotechnology, faced a web of increasingly comprehensive and strenuous national and international

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21. Parva Chhantyal, *How Polymer Nanoparticles Could Slow the Spread of COVID-19*, AZONANO, https://www.azonano.com/article.aspx?ArticleID=5537 (last visited Aug. 18, 2020).

22. Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 705 (2006) (explaining that impacted fields include space exploration, semiconductors, pharmaceuticals, energy, agriculture and more).

23. Rick Weiss, *Nanotech Poses Big Unknown to Science*, WASH POST, (Feb. 1, 2004) at A1, https://www.washingtonpost.com/archive/politics/2004/02/01/nanotech-poses-big-unknown-to-science/d4c653e5-bb98-4a86-bbba-3bd0de57b017/. *See also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-14-181SP, NANOMANUFACTURING: EMERGENCE AND IMPLICATIONS FOR U.S. COMPETITIVENESS, THE ENVIRONMENT, AND HUMAN HEALTH 13 (2014), http://www.gao.gov/assets/670/660591.pdf (stating that multiple participants selected by the National Academies of Science explained that nanomanufacturing could transform society as much as electricity, computers, and the internet.).

24. ETC calls for moratorium on nanotechnology products. Nat'l Nanotechnology Initiative, *supra* note 19; *see also* Brent Blackwelder, *Comment on a Framework Convention for Nanotechnology*, 38 ELR 10520, 10522 (2008) (stating how Friends of the Earth calls for an immediate worldwide moratorium on nanotechnology products until appropriate regulatory regimes are in place).

25. Mandel, *supra* note 17; Ortwin Renn & Mihail RC. Roco, *Nanotechnology and the Need for Risk Governance*, 8 NANOPARTICLE RES. 153, 172 (2006).

26. *E.g.*, Thomas Faunce and Bartlomiej Kolodziejczyk., *Nanowaste: Need for Disposal and Recycling Standards*, G20 INSIGHTS, (April 17, 2017) (arguing that G-20 member states should work together to regulate the field of nanotechnology and apply the Precautionary Principle to nanotechnology products but develop their own standards for nanowaste while coordinating to have "more unified international policies and guidelines"), available at https://www.g20-insights.org/wp-content/uploads/2017/05/Agenda-2030_Nanowaste-1.pdf; Gary E. Marchant, et al., *Transnational New Governance and the International Coordination of Nanotechnology Oversight*, papers.ssrn.com/id=1597809 (2010); Kenneth W. Abbott, et al., *Transnational Regulation: Reality or Romanticism?*, INT'L HANDBOOK ON REGULATING NANOTECHNOLOGIES, at 25 (2010); Gary E. Marchant et. al., *International Harmonization of Regulation of Nanomedicine*, STUDIES IN ETHICS, . & TECH. 3(3): Article 6 (2009); Linda Breggin, et al., *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, ENVTL. L. INST. & LONDON SCH. of ECON. (Sept. 2009), available at http://www.chathamhouse.org.uk/files/14692_r0909_nanotechnologies.pdf; Vladimir Murashov & John Howard, *The US Must Help Set International Standards for Nanotechnology*, 3 NATURE NANOTECHNOLOGY 635 (2008); Ken Abbott, et. al., *A Framework Convention for Nanotechnology*, 36 ELR 10507, 10507 (2008); *Response* by Lynn L. Begeson at 10515; David Rejeski, *Comment on A Framework Convention for Nanotechnology*, 38 ELR 10518 (2008); Diana M. Bowman & Graeme A. Hodge, *A Small Matter of Regulation: An International Review of Nanotechnology Regulation*, 8 COLUMBIA SCI . TECH. L. REV. 1, 2 (2007); Environmental Law Institute, *Symposium on Nanotechnology Governance: Environmental Management from an International Perspective* (2006); J. PELLEY & M. SANER, *International Approaches to the Regulatory Governance of Nanotechnology, Ottawa: Carleton University Regulatory Governance Initiative* (2009), available at http://www.carleton.ca/regulation/publications/Nanotechnology_Regulation_Paper_April2009.pdf; Gary E. Marchant,and Douglas Sylvester., *Transnational Models for Regulation of Nanotechnology*, 34 J. L MED. & ETHICS 714, 714 (2006).

27. Sabrina Safrin, *Anticipating the Storm: Predicting and Preventing Global Technology Conflicts*, 46 ARIZ. STATE L. J. 899, 902 (2014).

regulation—replete with mandatory risk assessments and expensive labeling regimes.[28] Meanwhile, the cellular phone, a technology that emerged and developed at precisely the same time, entered the marketplace with minimal health, safety, and environmental regulation.[29] Indeed, the primary international response to the cellphone was and has been the conduct of health and safety studies and the harmonization of standards that facilitate its spread.[30]

These vastly different regulatory responses find explanation neither in the two technologies' respective benefits nor in their respective risks. The dramatic regulatory discrepancy existed from the early days of the two technologies when scientists and regulators first identified the potential risks of each technology and before consumers benefited from either one.[31] In fact, AT&T originally forsook cellphone technology because it perceived only a small market for what was then an expensive gadget for the rich.[32] Scientific studies have shown the cellphone to present significantly greater health and safety risks than agricultural biotechnology.[33] Yet, the cellphone remains largely free from strenuous health and safety regulation, while agricultural biotechnology is encumbered by the same.[34] The different international regulatory climates impacted the fate of the twin technologies. The restrictive international environment slowed agricultural biotechnology.[35] The paucity of health, safety, and environmental regulation facilitated the cellphone's spread.[36] Is nanotechnology likely to face a strenuous international regulatory environment like that encompassing agricultural biotechnology, a modest response like that enjoyed by the cellphone, or something in between?

This article posits that an important early clue lies in the world's patent offices. Countries with early and significant patent activity by domestic inventors in an emerging technology are more likely to view themselves as having a national stake in that technology. They in turn will be more likely to resist having that technology subject to strenuous health, safety, and environmental regulation that would constrain the technology, particularly at an international level. Conversely, countries lacking meaningful patent activity by domestic inventors in an important emerging technology have less to lose from a restrictive regulatory landscape. They may even desire international health,

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28. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Articles 7–10, 15, Jan. 29, 2000, Montreal, 39 I.L.M. 1027 [hereinafter Biosafety Protocol].

29. Safrin, *supra* note 27, at 910, 912.

30. *Id*.

31. Safrin, *supra* note 27, at 913.

32. DAN STEINBOCK, THE NOKIA REVOLUTION: THE STORY OF AN EXTRAORDINARY COMPANY THAT TRANSFORMED AN INDUSTRY 112 (Amacom 2001).

33. *Infra* Part III(A).

34. *Infra* Part III(B).

35. Erik Dohlman, et al., *Regulatory Events and Biotech Firm Share Prices*, 24 REG. AGRIC. ECON. 108, 120 (2002) (explaining how equity values of leading biotechnology firms began to lag behind broader market indices in 1999 and 2000, having been highly valued relative to such indices in 1998. Companies began to reduce research efforts on new biotech seed development. "Regulatory events appear to covey the most negative information to investors regarding the prospects for future market expansion and profits."); ASA Calls EU Traceability and Labeling Review a Whitewash, AM. SOYBEAN ASS'N (May 10, 2006), https://soygrowers.com/news-releases/asa-calls-eu-traceability-labeling-review-a-whitewash/ (reporting a 65% drop in soybean exports following EU regulations on bioengineered food) [hereinafter ASA Calls EU].

36. ASA Calls EU, *supra* note 35.

safety, and environmental rules to restrain another country that they perceive as having a hegemonic presence in a new technology. Such rules could slow the hegemon's runaway advantage, even the global technological playing field, or enable lagging countries to extract concessions for the sharing of technological know-how and benefits between nations. In short, geographic diversity in patent activity for an important new technology may signal a low appetite on the part of governments for international regulation that could constrain that technology.

Before proceeding, two caveats are in order. First, this article does not argue that patents are the sole indicator of whether a major emerging technology will face a strenuous national and international health, safety, and environmental regulatory environment. Other factors such as catastrophic exogenous shocks,[37] institutional factors,[38] and cultural risk preferences[39] can play a role. Scholars have shown, for example, how cultural cognition of the risks and benefits of technologies may shape individual and societal receptivity to emerging technologies.[40] This author has shown how the ability of governments to directly capture economic benefits from an emerging technology, such as through the sale of spectrum rights, can soften potential opposition to a disruptive technology.[41] Moreover, patents may operate alongside government programs to foster a technology, indicating government support for the technology. As shown below, however, these programs usually lag patent activity.[42] Rather than asserting that patent footprints serve as a sole predictor of a disruptive technology's likely regulatory future, this article theorizes that patents serve as a particularly early, useful, and underestimated indicator of that future to be considered along with other factors.[43]

Second and similarly, this article does not suggest that patent footprints operate as a binary on-off switch. It does not posit that countries with an early and extensive patent presence in an emerging technology will never adopt a precautionary regulatory approach to the technology, or that countries with low patent activity will always pursue strenuous regulation.[44] Instead, this article argues that patent footprints provide a particularly early, if not the earliest, predictor of a country's likely predisposition to the extensive regulation of a disruptive technology as it balances uncertain environmental, health, and safety

37. CASS SUNSTEIN, LAWS OF FEAR 31–32 (Cambridge U. Press 2005).

38. POLLACK & SHAFFER, *supra* note 11, at 45–48.

39. *See generally* MARY DOUGLAS & AARON WILDAVSKY, RISK AND CULTURE (1983).

40. *E.g.*, Dan M. Kahan, et al., *Cultural Cognition of the Risks and Benefits of Nanotechnology*, 4 NATURE NANOTECHNOLOGY 87, 89 (2009) (concluding that people with "a pro-technology cultural orientation" are "more likely to become exposed to information about nanotechnology and to draw positive inferences from what they discover."); Dietram A. Scheufele & Bruce V. Lewenstein, *The Public and Nanotechnology: How Citizens Makes Sense of Emerging Technologies,* 7 NANOPARTICLE RES. 659, 663 (2005).

41. Safrin, *supra* note 27, at 914.

42. *See,* Lisa Larrimore Ouellette, *Nanotechnology and Innovation Policy*, 29 HARV. J. OF L. & TECH. 33, 34–36, 62–63 (2015) (recognizing that between 2000 and 2004, over sixty countries created national nanotechnology R & D programs.).

43. *See* Safrin, *supra* note 27, at 924–28 (analyzing how exogenous shocks, institutional factors, regulatory culture and cultural cognition theory do not fully explain the diametrically different approaches taken by the European Union and the United States to the health, safety, and environmental regulation of agricultural biotechnology nor to the various regulatory approaches to the cellphone).

44. *Id*.

concerns against its perceived economic future and techno-nationalistic interest in the technology.

Part I develops the theoretical basis for the predictive power of patents hypothesis. This Part explains why geographic diversity in patent activity could unexpectedly help predict the extent of health, safety, and environmental regulation that an emerging transformative technology might face, particularly at an international level. Part II then provides three suggestive illustrations of the geographic diversity of "patent footprints" for three major transformative technologies: 1) agricultural biotechnology, 2) the cellphone, and 3) nanotechnology. Part III proceeds to test the predictive power of patents theory by exploring the global regulatory environment that the three transformative technologies faced. The cases of agricultural biotechnology and the cellphone are particularly instructive given that the two technologies emerged and developed at the same time. They arose, therefore, in the same geopolitical, economic, and regulatory milieu. Nanotechnology presents a more recent case involving a major transformative technology where policymakers debate whether and how to regulate the new technology in the face of uncertainty of risk, including regulation at the international level.

II. THEORETICAL EXPLANATION FOR THE PREDICTIVE POWER OF PATENTS

Political economy scholars have shown that government officials weigh a myriad of factors when deciding whether and how to regulate a technology, which involve balancing the risks of the technology against its benefits.[45] In the context of nanomanufacturing, for example, the United States government in 2014 considered "implications for U.S. competitiveness" when evaluating how to approach risks to the environment and human health.[46] The United States is hardly alone in its framing. As Lisa Larrimore Ouelette points out, with respect to environmental and safety regulations over nanotechnology, "many governments have debated how to address concerns about negative impacts of nanotechnology without stifling innovation in the field."[47] Because the risks presented by a new technology are often hypothetical and uncertain, government officials exercise considerable discretion in deciding how to regulate them.[48] Countries acting in their economic self-interest ordinarily will want to bring their technology to market with minimum regulatory interference, and the ambiguity

45. Heba Shams, *Law in the Context of "Globalisation": A Framework of Analysis*, 35 INT'L L. 1589, 1596 (2001).

46. U.S. GOV'T ACCOUNTABILITY OFF., GAO–14–181SP, NANOMANUFACTURING: EMERGENCE AND IMPLICATIONS FOR U.S. COMPETITIVENESS, THE ENVIRONMENT, AND HUMAN HEALTH 13 (2014).

47. Ouellette, *supra* note 42, at 60.

48. *See* Gregory N. Mandel & Gary Marchant, *The Living Regulatory Challenges of Synthetic Biology*, 100 IOWA L. REV. 155, 158 (2014) (noting the challenges of regulating synthetic biology due to the technology's uncertain risks and benefits); Joy Y. Zhang et. al., *The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the 'Art' of Governance* 8 (Ctr. For the Study of Bioscience, Biomedicine, Biotechnology and Society, Working Paper No. 4, 2011), *available at* https://royalsociety.org/~/media/royal_society_content/policy/publications/2011/4294977685.pdf (discussing the role of uncertainty in international regulation of synthetic biology); and Mandel, *Nanotechnology Governance*, *supra* note 17 at 1326 (2008) (stressing the regulatory challenges posed by nanotechnology's uncertain risks).

of risk presents greater opportunity for domestic innovators and domestic economic self-interest to shape regulatory outcomes. Moreover, the presence of domestic innovators plays an important role in a nation's technology nationalism. With this in mind, this section explains why geographic diversity in patent footprints for an emerging technology can serve as an early predictor of whether governments might exercise their discretion to pursue a modest or more restrictive domestic and international regulatory regime for that technology.

A. The Nature of Patents

As a starting point, the predictive power of patents hypothesis girds itself in the nature of patents themselves. Patent footprints serve as a uniquely useful tool in predicting the regulatory future of an emerging technology because patents occur early in the innovative cycle but not too early. Theoretical breakthroughs such as Einstein's theory of relativity, Watson and Crick's 1972 discovery of the genetic double-helix, or Richard Feynman's famous "plenty of room at the bottom" 1959 speech that foresaw a nanotechnology future,[49] precede patent activity. These theoretical breakthroughs, however, come too early in the innovative cycle to trigger a regulatory response. Patents, in contrast, issue to applied technology. They bridge theory and adoption. They occur before consumers and countries shoulder the benefits and risks of the new technology but late enough that stakeholders and decision-makers can begin to anticipate whether their country stands poised to have a stake in the emerging technology.

While national plans to support a technology also indicate a country's interest in that technology, governments tend to establish these plans years after patent activity. For example, not until 2000 did the United States promulgate its national nanotechnology plan, years after thousands of nanotechnology patents had issued.[50] Over sixty countries followed suit with their own nanotechnology plans even later.[51] Thus, patents provide a considerably earlier harbinger of a country's future in a technology than do national plans.

B. Domestic Innovators and Technology Nationalism

Patent activity by a country's domestic inventors signals the presence of domestic innovators in a given field. Of course, patent activity is not the exclusive indicator of a domestic innovative presence. A country may have domestic innovators engaged in publicly funded research for which they may or may not have sought patent protection.[52] Even if not on par with the private

49. Richard Feynman, *Plenty of Room at the Bottom* (Dec. 1959) (lecture to the American Physical Society).

50. Ouellette, *supra* note 42, at 60.

51. *Id.*

52. *See Invention, Knowledge Transfer, and Innovation*, NAT'L SCI. BD. (last visited Jan. 28, 2021), https://ncses.nsf.gov/pubs/nsb20204/innovation-indicators-united-states-and-other-major-economies (describing that relative to the amount of R&D performed, universities and federal labs receive fewer patents. In 2017 and 2018, universities performed about 13% of R&D and received 4% of USPTO patents. Government

sector, however, universities and government-supported research organizations increasingly patent their innovations both in the United States and overseas.[53] Businesses engaged in research and development seek patent protection for their inventions,[54] and nationals of countries with robust inventiveness in a field patent their inventions both in their own countries and elsewhere.[55] While "there is more to invention than patenting," overall patents serve as the leading indicator of applied innovation[56] and robust patenting activity by a country's nationals indicates the presence of domestic innovators.

The presence of domestic innovators in turn increases the likelihood of a national interest group vested in the technology that can positively influence regulators who are deciding how to regulate that technology. Scholars have shown that a domestic group of innovators can exercise particular power in the case of rapidly developing emerging technologies where information asymmetry usually exists between innovators and innovative companies at the frontier of a technology and regulators who are trying to catch up.[57] At a minimum, the presence of domestic innovators increases the likelihood that the technology will have its champions when domestic regulatory decisions are being made.

In the case of disruptive emerging technologies that threaten to replace existing technologies, the presence of domestic innovators can serve as a counterweight to the lobbying efforts of industries harmed by the new technology. While industries adversely affected by a new technology may press for restrictive regulations to curtail the technology, the existence of domestic innovators in the new field increases the likelihood of a counter-group to

labs performed about 10% of R&D and received 1% of patents. "Research at universities and federal labs more frequently yields peer-reviewed articles than commercially oriented inventions. This disparity between R&D activity and patenting makes sense given the difference among the activities and goals of universities, federal labs, and businesses.").

53. Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L. J. 85, 105 (2007) ("New players, such as universities and scientific research organizations, routinely patent their output…"). In the case of nanotechnology, Mark Lemley found that "companies and universities alike are patenting early and often" and "a large number of the basic nanotechnology patents have been issued to universities, which have become far more active in patenting in the last twenty-five years." Mark Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601 (2005).

54. Reichman & Dreyfuss, *id*. The National Science Board found that in 2017 and 2018, 70% of the R&D performed in the United States was done by businesses and businesses received 85% of U.S. patents. NAT'L SCIENCE Board *supra* note 52.

55. See Jorge L. Contreras & Rohini Lakshane, *Patents and Mobile Devices in India: An Empirical Survey*, 50 VAND. J. OF TRANSNAT'L L. 3 , 31 (2017) (describing how multinational players in mobile devices, such as Apple, Samsung, Motorola, Qualcomm, and Alcatel-Lucent, have amassed massive patent portfolios and have patented their inventions not only in developed world countries but in India. Meanwhile, Indian firms engaged in pharmaceutical innovation file a substantial number of pharmaceutical patents both in India and overseas).

56. Reichman & Dreyfuss, *supra* note 54, at 106. *But see* Contreras & Lakshane, *supra* note 55 at 4,33 (noting the paucity of Indian patents by Indian nationals over mobile phone technology, even though Indian nationals have been innovating in the sector.) These unpatented innovations, however, are recent, draw upon previous-generation technology, and may be using technology patented by others for which there may be growing patent infringement exposure. *Id.* at 4, 33 and Jorge Contreras, *Patent-less Smartphone Innovation and Global Technology Markets*, PATENT PROGRESS (Dec. 19, 2012), http://www.patentprogress.org/2012/12/19/patnet-less-smartphone-innovatoin-and-global-technology-markets/.

57. *See* Gregory D. Graff & David Zilberman, *Explaining Europe's Resistance to Agricultural Biotechnology*, 7 AGRIC. & RESOURCES ECONOMICS 1, 2 (2004).

advocate for the technology.[58] Political economists have shown that regulators display greater sensitivity to domestic interests than to foreign ones.[59] Thus, the presence of domestic innovators holds particular importance when regulators weigh the benefits and risks of an emerging technology.

Moreover, countries with early and significant patent activity in an emerging technology are more likely to view themselves as having a future in that technology. They therefore will be more inclined to want that technology to blossom and less inclined to constrain it through extensive regulation. A growing body of scholarship points to the expanding role that "techno-nationalism" plays in countries' perception and furtherance of their overall national goals. Techno-nationalism views creating and capturing technological innovation as central to a nation's security and wealth.[60] Nations want their domestic industries to be market leaders in high-technology sectors.[61] The existence of domestic innovators is key to that agenda and patents by domestic innovators evidence their presence. Sapna Kumar shows how since the 1970s, the U.S. government, for example, has "actively promoted a national identity of innovativeness" and tied that identity to robust patent law.[62] This trend has accelerated both in the United States and overseas. President Obama stressed that "[t]he first step in winning the future is encouraging American innovation" and that the United States needed to "out-innovate" other countries.[63] China and some European nations have sought to emulate the United States in terms of innovative presence.[64]

In sum, the presence of domestic innovators in an emerging technology makes it less likely that domestic regulators will exercise their discretion in the face of ambiguity of risk to restrain the technology, both because of a domestic constituency to champion the technology and a perceived national stake in the technology's future that comports with its technology nationalism goals.

C. Impact on International Rulemaking

The two factors discussed above affect international rulemaking in two ways. First, countries that see themselves as having a future in a technology

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58. *See generally*, CALESTOUS JUMA, INNOVATION AND ITS ENEMIES: WHY PEOPLE RESIST NEW TECHNOLOGIES (2016) (describing resistance to technologies by industries about to be replaced).

59. Graff & Zilberman, *supra* note 57, at 2.

60. Olga Petricevic & David J. Teece, *The Structural Reshaping of Globalization: Implications for Strategic Sectors, Profiting from Innovation, and the Multinational Enterprise*, 50 J. INT'L BUS. STUD. 1487, 1495 (2019). *See also* Alex Capri, *Techno-Nationalism: What is it and How Will it Change Global Commerce?* FORBES (Dec. 20, 2019), http://www.forbes.com/sites/alexcapri/2019/12/20/techno-nationalism-what-is-it-and-how-will-it-change-global-commerce/?sh=4ab1fa24710f (providing commentary on the emerging techno-nationalist "strain of mercantilist thinking").

61. S. OSTRY & R.R. NELSON, TECHNO-NATIONALISM AND TECHNO-GLOBALISM: CONFLICT AND COOPERATION (1995).

62. Sapna Kumar, *Innovation Nationalism*, 51 CONN. L. REV. 205, 226–32 (2019).

63. *Id.* at 228–29 (quoting Dr. Patrick Gallagher, the Undersecretary of Commerce under President Barack Obama, that promoting technological innovation formed the "centerpiece" of Obama's economic agenda).

64. *Id.*; *see also* Petricevic & Teece, *supra* note 60, at 1490–91 (describing China's goal to achieve innovative dominance); David E.H. Edgerton, *The Contradictions of Techno-Nationalism and Techno-Globalism: A Historical Perspective*, 1 NEW GLOBAL STUD. 1, 2 (2007) (detailing the evolution of techno-nationalism and techno-globalism).

because of the presence of domestic innovators are less likely to promulgate overly restrictive health, safety, and environmental rules as a domestic matter. Having chosen a less restrictive domestic regulatory path, they will similarly, if not more so, eschew a restrictive regime internationally. Countries will rarely bind themselves to restrictive rules internationally that they had affirmatively decided against domestically. After all, international regulations curtail the power of domestic regulators. Any domestic legislation to implement the international standards will be difficult to obtain in the face of a domestic constituency championing a technology and a domestic regulatory apparatus opposed to restrictive rules. Moreover, modifications to international rules require the approval of multiple countries, making them particularly difficult to change.[65] International regulation of a technology can straitjacket domestic regulators for years to come. Countries wishing to see a new technology flourish will find binding international rules particularly unsavory, given the need for flexibility in the face of uncertain risks and domestic implementation challenges.[66]

If anything, countries will seek to harmonize international rules to their own standards[67] rather than embark on more stringent international rules that curtail their flexibility. We see this phenomenon in the development of international telecommunication standards where countries strove to conform international standards to their domestic ones.[68] Similarly in the case of biotechnology, the EU sought international rules to match its domestic rules, while the United States opposed international rules that went beyond its chosen level of protection domestically.[69] In sum, a relationship exists between the domestic regulation of a technology and the likelihood of its international regulation. Countries that have decided against the strict domestic regulation of a technology or that wish to preserve domestic flexibility will not generally favor subjecting the technology to strict constraints as a matter of international law.

Second, the cost-benefit calculus for international environmental, health, and safety rules changes significantly when few countries have innovative capacity in a technology. This is even more so when a single country dominates a technological field, becoming what we call a "technological hegemon." For countries outside of this single or small innovative clique, a decision to impose

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65. Gregory C. Shaffer & Mark A. Pollack, *Hard v. Soft Law in International Security*, 52 B.C. L. REV. 1147, 1163 (2011).

66. *See generally, id.* at 1163–64; *see also* David G. Victor, Kal Raustiala, & Eugene B. Skolnikoff, IMPLEMENTATION & EFFECTIVENESS OF INT'L ENV'T COMMITMENTS: THEORY & PRACTICE, at 781 (1998) ("When uncertainty has been high, most governments have approached binding commitments with caution: they have signed only what they could implement, and thus binding commitments have typically required only modest, if any, change in behavior *ex ante*…").

67. Shaffer & Pollack, *supra* note 65 at 1177. *See also* William W. Burke-White & Anne-Marie Slaughter, *The Future of International Law is Domestic (or, The European Way of Law)*, 47 HARV. INT'L L.J. 327, 335–336 (2006) (describing the export by both the U.S. and the EU of their regulatory approaches in the areas of securities, antitrust, environmental and competition policy through informal transnational networks).

68. *See* Mustafa M. Matalgah, *International Mobile Telecommunications – 2000 and 3G Wireless Systems*, *in* HANDBOOK OF COMPUT. NETWORKS, at 716 (explaining that international recommendations and guidance on spectrum bandwidth and band of operation are based on critical technical parameters and traffic estimates).

69. Shaffer & Pollack, *supra* note 65, at 1177.

strict international environmental, health, and safety rules does not come at the cost of curtailing a potential domestic industry in the emerging technology. On the contrary, countries without technological capacity may wish to protect their domestic industries from displacement or harm from the emerging technology. They stand to benefit from international rules that would slow the technology down. For example, during the negotiation of the Biosafety Protocol, a multilateral agreement governing the trade in bioengineered goods, some developing countries advocated strict rules out of fear that "arctic" rice and coffee, bioengineered to grow in cold climates, would displace their important temperate climate cash crop exports.[70]

International regulations can better restrict a technology than domestic ones due to their global reach. In addition, international health, safety, and environmental regulations become even more attractive to countries wishing to curtail a technology when they factor in the World Trade Organization (WTO) trade disciplines. The international trade rules favor international health, safety, and environmental regulations over purely domestic ones. In particular, the WTO Sanitary and Phytosanitary (SPS) Agreement prohibits countries from enacting health, safety, and environmental regulations when promulgated as disguised barriers to trade.[71] The SPS Agreement presumes that international health, safety, and environmental rules lack this nefarious purpose and hence presumes them to be WTO compliant.[72] Incentive therefore exists for countries that wish to restrain a disruptive emerging technology to have restrictive rules promulgated at the international level. Not only will international rules better restrain the technology as they will govern multiple nations, but they will also shield a country that wishes to protect its domestic industry from trade sanctions under the WTO.

It bears noting that international rulemaking usually requires either consensus or super-majorities.[73] Thus, even if the overwhelming majority of countries lack innovative capacity in an emerging technology, as long as a powerful minority exists with innovative capacity, that minority can block consensus or a supermajority from forming. This minority can prevent the promulgation of restrictive environmental, health, and safety rules. When considering geographic diversity in patent footprints, therefore, one need not see a majority of nations involved in nascent technology. Rather, patent footprints must simply exist across geographic groups capable of blocking consensus and, most of all, the technology must not concentrate in a single country.

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70. Author participated in the negotiation of the Biosafety Protocol and heard these concerns.

71. *Agreement on the Application of Sanitary and Phytosanitary Measures*, 1867 U.N.T.S. 493 (Jan. 1, 1995) [hereinafter SPS Agreement] at Annex 1A, Art. 2(3); KEVIN C. KENNEDY, INTERNATIONAL TRADE REGULATION 367 (2009).

72. David G. Victor, UCIAS DYNAMICS OF REGULATORY CHANGE: HOW GLOBALIZATION AFFECTS NATIONAL REGULATORY POLICIES 3–4 (2002).

73. Eric A. Posner & Alan O. Sykes, *Voting Rules in International Organizations* 2 (U. Chi. Coase-Sandor Inst. For L. & Econ., Working Paper No. 458, 2014).

III. PATENT FOOTPRINTS

We now turn to an exploration of the patent footprints in three major disruptive technologies. This Part will analyze whether multiple nations have innovated in these technologies such that they would hesitate to constrain the technologies with extensive health, safety, and environmental regulation, particularly at an international level. In the alternative, was the disruptive technology characterized by a single country with a runaway or hegemonic presence in the technology that might cause other countries to pursue strict international health, safety, and environmental rules to slow the hegemon's runaway advantage?

A. Approach

To assess geographic diversity in patent activity we have relied primarily on the country of origin of the named inventor in U.S. patents. The use of the country of origin of the named inventor as a metric for ascribing country "credit" for an invention is not unique. Both the U.S. Patent and Trademark Office (USPTO) and the Organization for Economic Cooperation and Development (OECD) publish datasets on inventors' country of origin to help ascertain who is patenting what.[74] Other scholars have similarly used the country of origin of the named inventor in U.S. patents to determine geographic patent activity.[75] Admittedly, the use of U.S. patents to assess geographic diversity in patent activity suffers from a "home advantage" effect, whereby the U.S. Patent Office would receive proportionately more patent applications from U.S. inventors than from foreign ones.[76] However, given the size of the U.S. market and the importance to foreign inventors of protecting key innovations in the United States,[77] a home-court bias in the USPTO in favor of U.S. inventors would not explain dramatic differences in foreign inventive activity between technologies. Moreover, the presence of significant foreign inventor activity in the United States would anticipate even greater non-U.S. inventor activity in a given technology in patent offices overseas. In other words, if nearly half of U.S. patents in a technology class are issued to foreign inventors, the home advantage effect would suggest an even greater geographic diversity of patent activity in an emerging technology in overseas patent offices.

In addition, we have considered the literature on the patent quality of patents in the three examined technological fields. The quantity of patent activity in a given technological field points to the extent of innovative activity

74. *See Data for Researchers*, WIPO, https://www.wipo.int/econ_stat/en/economics/research/ (last visited Jan. 31, 2021) (providing a hub to all datasets for all WIPO-affiliated intellectual property offices).

75. *See* Graff & Zilberman, *supra* note 59 (describing an instance of such a method of identification).

76. *See* Paolo Criscuolo, *The 'Home Advantage' Effect and Patent Families: A Comparison of OECD Triadic Patents, the USPTO and EPO*, 66 SCIENTOMETRICS 23, 30 (2006) (describing the "home advantage" effect); EUR. Commission, *Second European Report on S & T Indicators* (1997) (showing European inventors primarily applied for patents in Europe).

77. *See* Brian J. Love et al., *An Empirical Look at the "Brokered" Market for Patents*, 83 MO. L. REV. 359, 372 (2018) (stressing the importance and value of U.S. patent rights given the size of U.S. technology markets).

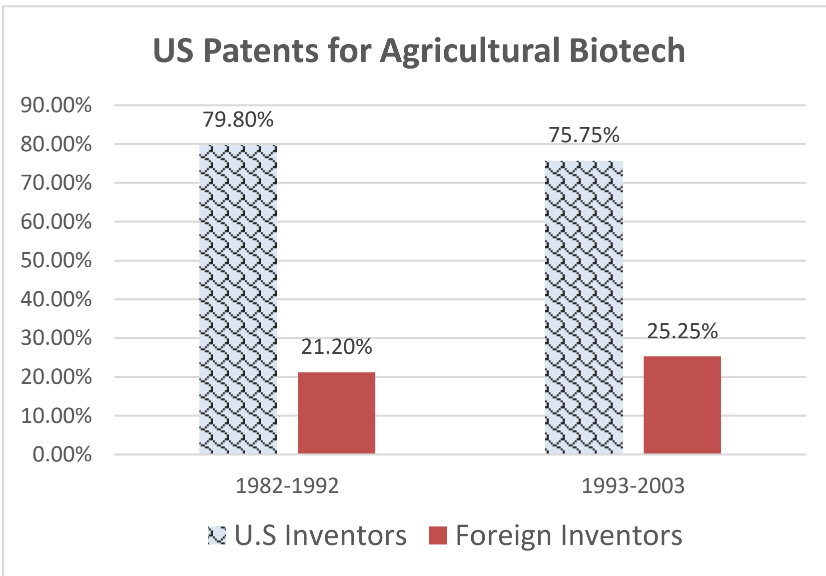
in that field, while an analysis of patent quality provides a fuller picture of the value of the innovations patented.

Finally, we have focused our analysis on the foundational periods of each technology but have at times fleshed out that analysis with an exploration of later patent activity.

B. Illustrations

1. Agricultural Biotechnology

An analysis of patent activity reveals that from the earliest days, U.S. inventors and U.S. firms dominated agricultural biotechnology. Between 1982–1992, the foundational decade for agricultural biotechnology, U.S. inventors received 79% of U.S. patents in the class most relevant to agricultural biotechnology.[78] Between 1993–2003, they received 75% of such patents.[79] Overall, between 1963–2011, U.S. inventors received three times as many patents in the class most relevant to agricultural biotechnology than their foreign counterparts.[80]



78. Safrin, *supra* note 27, at 930. Author culled data from U.S. PAT. OFF., PATENTING BY GEOGRAPHIC REGION BREAKOUT BY TECHNOLOGY CLASS COUNT OF 1963-2011 UTILITY PATENT GRANTS, (129 patents issued to U.S. inventors compared to 34 issued to foreign inventors in technology class 800) [hereinafter USPTO REPORT]; *see also* Gregory D. Graff & David Zilberman, *Explaining Europe's Resistance to Agricultural Biotechnology*, 7 AGRIC. & RESOURCES ECON. UPDATE 1, 3 (2004) (finding that in the foundational decades of agricultural biotechnology, 1982–2002, North American inventors received 3,035 U.S. patents covering "agbiotechnologies and crop genetics," while European inventors received only 774 patents).

79. USPTO REPORT, *supra* note 78 (citing 2,821 issued to U.S. inventors compared to 944 issued to foreign inventors).

80. *Id.* (citing 7,515 patents issued to U.S. inventors compared to 2,443 patents issued to foreign inventors).

By way of a baseline comparison, between 1982–1993 and 1993–2003, 45.3% and 44.1% of all U.S. patents were issued to foreign inventors, respectively.[81] Thus, foreign inventive activity as compared to U.S. inventive activity in the agricultural biotechnology sector fell far below the norm.

Moreover, agricultural biotechnology patents granted to U.S. inventors manifest greater value or quality than those granted to their foreign counterparts.[82] In other words, not only were U.S. inventors receiving seventy-five to eighty percent of patents relevant to agricultural biotechnology, they were also receiving the most important ones. Scholars track the number of citations that a patent receives from other patents as one way to test a patent's value.[83] Since 1980, agbiotech patents granted to U.S. inventors have on the whole received ten times more patent citations than those granted to European inventors.[84] Graff and Zilberman find this difference particularly pronounced during the 1980s and early 1990s, the foundational years of the technology and before there existed much public awareness of, let alone opposition, to it.[85] We cannot, therefore, explain the difference in innovative capacity as primarily due to a flight of agricultural biotechnology research and development from a hostile Europe, though this flight did eventually occur. In sum, the patent footprints in agricultural biotechnology show that the United States held a commanding innovative lead in this sector.

Overall, the patent footprints for agricultural biotechnology reveal that the United States had a hegemonic presence in the technology. No other country came close to its innovative heft.

2. *Cellphone Technology*

Unlike agbiotech patents, patent ownership and innovation in telecommunications as well as in digital communications, the two patent classes covering cellular communications, displayed global diversity in the foundational years of the technology. In sharp contrast to agricultural biotechnology, where U.S. inventors have received approximately 75% of U.S. patents issued, foreign inventors have received about as many U.S. patents in the fields of digital or pulse communications and telecommunications as their U.S. counterparts. Between 1982–1992, the foundational decade for cellphone communications, U.S. inventors received 51% and foreign inventors received 49% of U.S. patents for digital or pulse communications[86] and 56% and 44% respectively of U.S.

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81. U.S. PAT. OFF., U.S Patent Statistics Chart CALENDAR YEARS 1963–2019, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited June 5, 2020).

82. Gregory D. Graff et al., *The Political Economy of Agricultural Biotechnology Policies*, 12 AGBIOFORUM 34, 39 (2009).

83. *Id.*

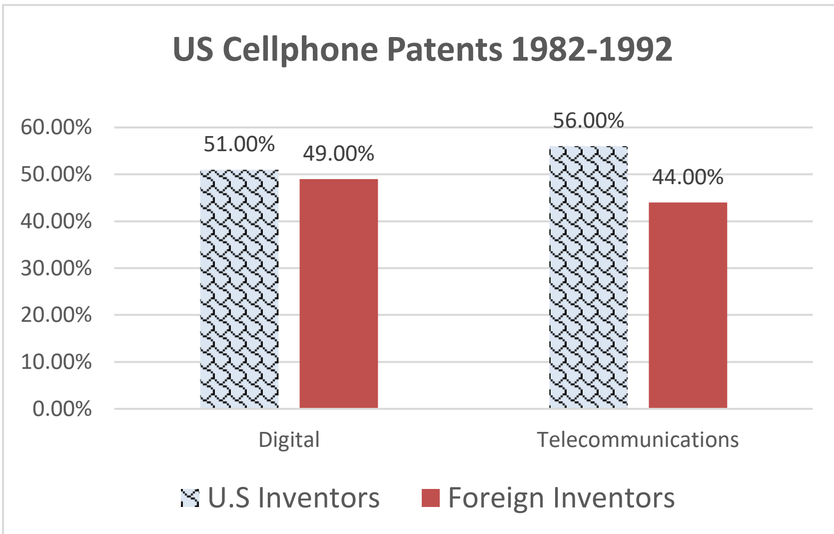
84. *Id.*

85. *Id.* at 39–40.

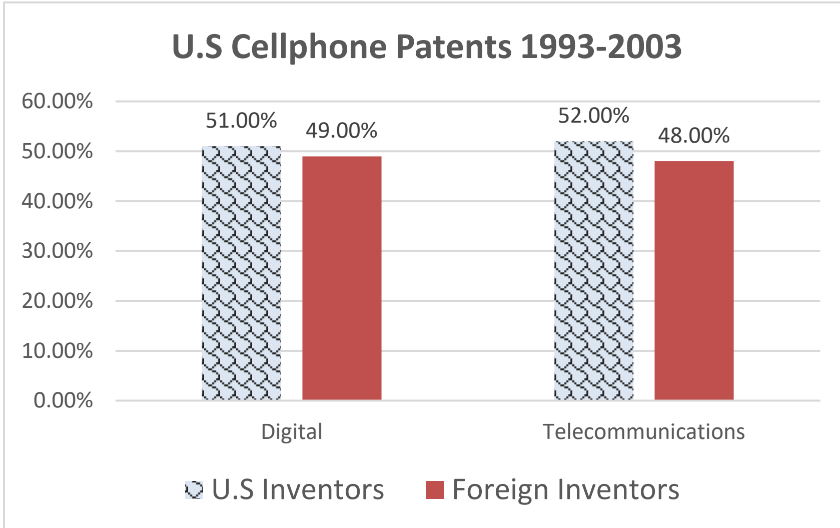
86. Safrin, *supra* note 27, at 930. Author culled data from United States Patent Office, PATENTING BY GEOGRAPHIC REGION BREAKOUT BY TECHNOLOGY CLASS COUNT OF 1963–2011 UTILITY PATENT GRANTS available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecstca/294clstc_gd.htm (last visited Jan. 13, 2016) (citing that in the digital or pulse communications field, the U.S. patent office granted U.S. inventors 1681 patents and foreign inventors 1593 patents).

telecommunications patents.[87] In the next decade, 1993–2003, U.S. inventors received 51% and foreign inventors received 49% of U.S. patents in the field of digital or pulse communications,[88] and 52% and 48%, respectively, of U.S. telecommunications patents.[89] Foreign inventors in the fields most relevant to cellphone technology received more patents than the baseline norm in these two decades.

Overall, between 1963 and 2011, foreign inventors received almost as many U.S. patents as did U.S. inventors in the fields key to cellphone communications. The U.S. patent office granted U.S. inventors 24,128 and foreign inventors 22,696 telecommunications patents: 51.5% to 48.5%.[90] U.S. inventors received 18,103 digital communications patents compared to 17,222 received by foreign inventors: 51% to 49%.[91]



87. *Id.* (citing 1,314 patents to U.S. inventors and 1,024 patents to foreign inventors).
88. *Id.* (citing 6,027 patents to U.S. inventors and 5,748 to foreign inventors).
89. *Id.* (citing 6,659 patents to U.S. inventors and 6,177 patents to foreign inventors).
90. *Id.*
91. *Id.*



Moreover, in contrast to agbiotech patents, patents owned by foreign corporations relevant to cellphone technology have manifested comparable value or quality as those owned by U.S. corporations. For example, a 2004 survey examined the ownership of the 7,796 patents important for third generation cellphone technology.[92] Of the 265 patents determined by the survey authors to be most essential, Finnish Nokia owned 55 (21%), Swedish Ericsson owned 34 (13%), and U.S. Qualcomm and Motorola together owned 109 (41%), with others owning the rest.[93] Forty-one different companies owned patents key to third generation technology.[94]

In sum, an analysis of the geographic diversity in patent activity reveals a dramatic difference in the patent activity of U.S. versus foreign inventors in the agricultural biotechnology sphere as compared to fairly comparable patent activity between U.S. and foreign inventors in the technological sectors implicating cellular phone technology in the foundational decades of each technology.

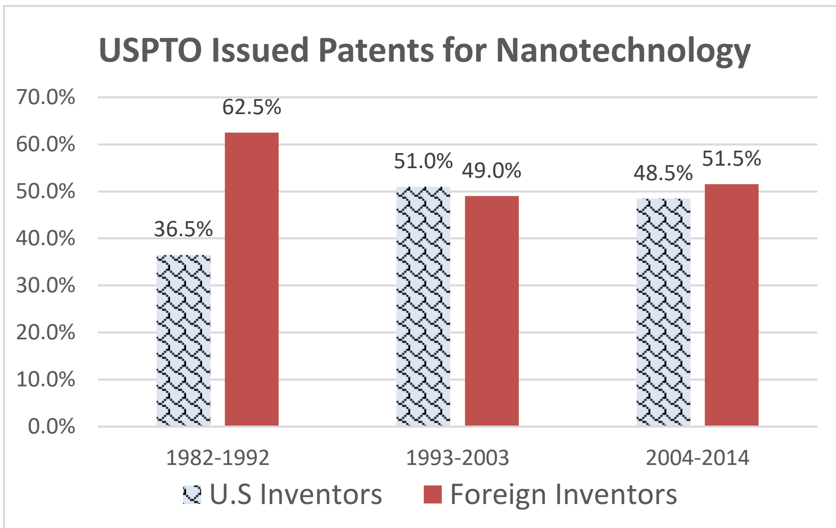
3. *Nanotechnology*

Turning to nanotechnology, we find that its patent footprint more closely resembles that of the cellular telephone than that of agricultural biotechnology. Our empirical analysis of patent activity in the nanotechnology sector reveals the lack of a single nation exercising hegemonic innovative dominance. Rather, early patent activity indicates that, as with the cellphone and in contrast to

92. David J. Goodman & Robert A. Myers, *3G Cellular Standards and Patents*, IEEE WIRELESSCOM 2005, at 4 (June 13, 2005).
93. *Id.* at 4.
94. *Id.*

agricultural biotechnology, numerous nations actively and extensively engage in innovation in the nanotechnology field. Unfortunately, the USPTO has not compiled yearly datasets on the country of inventors' origin for nanotechnology.[95] OECD, however, does maintain statistics for nanotechnology that indicates the number of U.S.-issued patents by inventor country of origin.[96]

Between 1982 and 1992, the nascent years of the nanotechnology sector, USPTO issued 36.5% of patents to U.S. inventors and 62.5% to foreign inventors.[97] Between 1993 and 2003, USPTO issued 51% of patents to U.S. inventor and 49% to foreign inventors.[98] Between 2004 and 2014, the USPTO issued 48.5% of patents to U.S. inventors and 51.5% to foreign inventors.[99] Like the cellphone, and in contrast to agricultural biotechnology, foreign inventive activity in the nanotechnology sector exceeded the baseline norm during these decades.



Statistics of patent activity under the Patent Cooperation Treaty (PCT) similarly reveal a lack of a technological hegemon in the nanotechnology

95. Jordan Paradise, 10 N.W. J. OF TECH. & INTELL. PROP. 169, 190 (2012). USPTO technology class for nanotech is 977. The USPTO established this class in 2004 and did not retroactively classify already issued nanotech patents into the 977 technology class, except on an ad-hoc basis.

96. *Science, Technology, and Patents*, OECD. STAT, https://stats.oecd.org/Index.aspx?DataSetCode+PATS IPC (last visited June 3, 2020). OECD's method of counting inventors' country of origin differs from the USPTO's way of counting inventors' country of origin. The USPTO uses the country of origin of the first named inventor as the country of origin for the patent. This makes sense because the first named inventor is the lead inventor. OECD uses a fractional count approach when there are multiple inventors from different countries. For example, if an invention is made by one inventor from the United States, one from France and two from Germany, OECD counts the invention as having been made 50% from Germany, 25% from France and 25% from the United States. The different methods of ascribing country of origin should not have a material effect on the overall analysis because they are applied across the board in a large dataset and therefore should even out. We have no reason to believe that the inventor from United States would consistently be the first inventor.

97. *Id.*

98. *Id.*

99. *Id.*

sector.[100] Between 1999 and 2009, 43% of patent applications filed under the PCT in the nanotechnology sector were by U.S. inventors and 57% of such patent applications were by foreign inventors.[101] Moreover, we see foreign inventive activity relative to U.S. inventive activity increasing over time. For example, between 1999 and 2001, 52% of PCT patent applications in the nanotechnology field were by U.S. resident inventors.[102] Between 2010 and 2012, that number dropped to 35%.[103]

In terms of the quality of nanotechnology patents, an analysis by Chen, Roco, Li, and Lin found that although the United States has more patent publications in the nanotechnology sector than any other country, patents from a number of other countries have comparable and at times even higher average impact on the nanotechnology field.[104] Chen et al. found that nanotechnology patents issued by the USPTO cited Swiss and Japanese nanotechnology patents almost as often as they cited other U.S. issued nanotechnology patents.[105] U.S. patents were cited an average of 2.49 times while Swiss and Japanese patents clocked in at 2.44 and 2.2 times, respectively.[106] At the European Patent Office, patents issued outside the United States enjoyed higher or equal citation counts to U.S. patents. Japanese patents were cited an average of .19 times, Belgium patents .15 times and South Korea and Switzerland both .10 times compared to the .10 citation rate of U.S. patents.[107]

In addition, some scholars have noted that nanotechnology patents tend to have numerous inventors from more than one institution and from more than one country and reveal extensive multinational collaborations on inventions.[108] An analysis of pending nanotechnology patents by Sylvester and Bowman, for example, found collaborations on inventions between U.S. inventors and inventors from India, Great Britain, the Netherlands, Poland, Belgium, and Japan.[109]

C. Conclusion

From a political economy perspective, the patent footprints in the agricultural biotechnology sphere revealed the existence of multiple major U.S. patent-obtaining organizations, which stood poised to influence U.S. regulators,

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100. *Id.* (reporting on yearly PCT patent applications in the nanotechnology sector by inventor's country of residence from 1999–2012).

101. *Id.* (reporting 18,287 patent applications were filed in the nanotechnology sector. Of these, 7,805 patent applications listed a U.S. resident inventor.)

102. *Id.* (reporting 3,079 nanotechnology patents filed worldwide, of which 1,591 included a U.S. resident inventor).

103. *Id.* (reporting 5,818 patent applications filed worldwide, of which 2,008 included a U.S. resident inventor).

104. Hsinchun Chen et. al., *Trends in Nanotechnology Patents*, 3 NATURE NANOTECHNOLOGY 123, 124 (2008).

105. *Id.*

106. *Id.*

107. *Id.*

108. Douglas J. Sylvester & Diana M. Bowman, *Navigating the Patent Landscape for Nanotechnology: English Garden or Tangled Grounds?*, BIOMEDICALTECHNOLOGY METHODS AND PROTOCOLS, at 9–10. (Sarah J. Hurst, ed., 2011).

109. *Id.* at 10.

and a relative dearth of foreign patent-obtaining organizations ready to exercise similar influence with regulators overseas. According to the USPTO, based on a period spanning 1969–2013, ten of the top fifteen patent obtaining organizations in the technological class most pertinent to agricultural biotechnology came from the United States.[110] These included powerful corporations like Monsanto and Pioneer Hi-Bred.[111] Only two European and two Swiss companies made the list: German BASF Plant Science, Belgium CropDesign and Swiss Syngenta and Mertec Ag.[112] Combined, the European companies had only 146 patents and the Swiss ones 504, compared to the whopping 6,376 patents issued to U.S. corporations on the list.[113]

In contrast, patent footprints in the cellular telecommunications field demonstrate geographic diversity. Multiple major overseas patent-obtaining organizations existed that could influence overseas regulators. USPTO statistics show that between 1969–2013, only three of the top fifteen organizations obtaining U.S. patents in telecommunications came from the United States (Motorola, Qualcomm, and Broadcom).[114] The remainder hailed from Japan, South Korea, Finland, France, Sweden, and Canada.[115] While not in the top fifteen, Germany's Siemens was a major telecommunications patent-obtaining entity as well.[116] Moreover, patent ownership spreads among these countries rather than concentrating in a single country or company. Of the top fifteen patent-obtaining organizations, taken together, U.S. companies on this list received 6,107 patents, European companies received 6,126 patents, Japanese companies received 5,234 patents, South Korean companies received 3,392 patents, and the top Canadian company received 1,137 patents.[117]

In the case of nanotechnology, a study by Li, Lin, Chen, and Roco of USPTO published nanotechnology patents between 1976–2004 reveal a patent distribution among top assignee entities that lies somewhere between agricultural biotechnology and cellphone technology.[118] Of the top twenty nanotechnology patent obtaining entities, twelve came from the United States.[119] This includes the number one and number two patent obtaining entities: IBM and the Regents of the University of California.[120] However, unlike agricultural biotechnology where U.S. entities held all of the top spots, in nanotechnology,

110. *Extended Year Set – Patenting in Technology Classes, Breakout by Organization 1969–2013 Utility Patent Grants with Patent Counts Based on Primary Patent Classification, Technology Class 800*, U.S. PAT. & TRADEMARK OFF., http://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecasg/800_tor.htm (last visited Feb. 21, 2021) [hereinafter *Utility Patent Grants*].

111. *Id.*

112. *Id.*

113. *Id.*

114. *Extended Year Set – Patenting in Technology Classes, Breakout by Organization*, U.S. PAT. & TRADEMARK OFF. (last modified Mar. 26, 2014, 9:17 AM), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecasga/455_torg.htm.

115. *Id.*

116. *See id.* (showing Siemens Aktiengesellschaft receiving 479 Telecom patents between 1969 and 2015).

117. *See id.* (including patents obtained by Nokia Mobile Phones LTD and Nokia Telecommunications OYJ with patents obtained by Nokia Corporation.)

118. Xin Li et al., *Worldwide Nanotechnology Development: A Comparative Study of USPTO, EPO, and JPO Patents (1976–2004)*, 9 J. NANOPARTICLE RSCH. 977 (July 27, 2007).

119. *Id.* at 988.

120. *Id.*

Japanese and French organizations held six of the top eight spots.[121] Overall, the nanotechnology sector manifests less geographic diversity in patent activity than occurred with cellphone technology but considerably more diversity than occurred with agricultural biotechnology. Moreover, as was true with cellphone technology and in contrast to agricultural biotechnology, the productivity of the top U.S. nanotechnology patent-obtaining entity (IBM) declined in the later years.[122] Furthermore, patents largely spread among the remaining institutions rather than concentrating in a couple of runaway corporations like Monsanto or Pioneer HiBred.[123] Japanese Matsushita, Toshiba, and Hitachi and French L'Oreal obtain a comparable number of patents to U.S. Xerox, Texas Instruments, GE, and Hewlett-Packard.[124] Overall, unlike agricultural biotechnology and similar to cellular telephone technology, multiple powerful overseas patent-obtaining organizations, like L'Oreal, Toshiba, Hitachi, Matsushita Electric Industrial Co., and Allied Signal, existed and exist in the nanotechnology sphere that could and can influence regulators in foreign countries.

Finally, the patent footprints of agricultural biotechnology indicate that the United States stood as a technological hegemon in that technology. In contrast, the patent footprints of cellphone technology and nanotechnology reveal the lack of a technological hegemon. Multiple countries were and are innovating in these emerging fields. Therefore, from a geopolitical perspective, they lacked compelling motivation to fear and restrain a hegemon with a runaway advantage in the nascent technologies.

IV. Application of the Predictive Power of Patents Theory

A. Background on the Risks of the Three Technologies

Before exploring the national and in turn international regulatory response to the three technologies, a brief primer on the health, safety, and environmental risks posed by each technology is in order. The potential risks of these technologies have been analyzed at length elsewhere, and the discussion below summarizes the core concerns.

1. Agricultural Biotechnology

Turning first to agricultural biotechnology, consumption of bioengineered food presents two main risks to human health. First, bioengineered food might unwittingly trigger an allergic reaction.[125] For example, oranges bioengineered with a gene from a flounder to resist frost could hypothetically trigger an allergic

121. *Id.*
122. *Id.* at 986.
123. *Id. Cf. Utility Patent Grants*, *supra* note 110 (displaying large disparity between the top two organizations and everyone else).
124. Li, *supra* note 118, at 988.
125. Peter Pringle, Food, Inc.: Mendel to Monsanto—The Promises and Perils of the Biotech Harvest 60 (2003).

reaction in people allergic to fish when eating the bioengineered orange. To date, these allergenicity concerns have not born out in practice.[126] Scientists can and do test food to ensure that they have not transferred allergens from one food to another, and people do not appear to be having allergic reactions to transferred genes.[127] Second, crops bioengineered to resist pests could unintentionally prove to be toxic.[128] Most importantly, genes from the common soil bacterium *Bacillus thruingiensis* (*Bt*), routinely used by organic gardeners as a spray on insecticide, have been widely transferred to potatoes, corn, and cotton to enable them to resist pests.[129] Numerous governments have conducted acute toxicity tests on *Bt* crops and found them non-toxic to humans.[130] For example, after six years of review the government of the Philippines found *Bt* corn unharmful to humans because the *Bt* protein only affects organisms with specific receptor sites in their alkaline guts, which humans lack.[131]

The European Union spent $425 million over twenty-five years studying the safety of genetically-modified crops.[132] An extensive report issued in 2010 by the European Commission Directorate General for Research and Innovation concluded that, based on the efforts of more than 130 research projects involving more than 500 independent research groups, genetically modified foods are not more risky than conventional plant breeding technologies.[133] A 2009 report commissioned by the European Union similarly concluded that genetically-modified foods pose no greater danger to human or animal health than their conventional counterparts.[134]

A potential indirect health risk of agricultural biotechnology has emerged, caused not by human consumption of or direct exposure to genetically-modified crops, but from extended human exposure to the world's most popular weed-killer, glyphosate-based herbicide Roundup.[135] Roundup is a conventional

126. U.S. FOOD & DRUG ADMIN., GMOS & YOUR HEALTH (2020), https://www.fda.gov/media/135280/download

127. *Id.*

128. PRINGLE, *supra* note 125, at 60.

129. DANIEL LEE KLEINMAN, SCIENCE AND TECHNOLOGY IN SOCIETY: FROM BIOTECHNOLOGY TO THE INTERNET 16 (2005).

130. *See, e.g.*, ENV'T PROT. AGENCY, BIOPESTICIDES REGISTRATION ACTION DOCUMENT: BACILLUS THURINGIENSIS (BT) PLANT-INCORPORATED PROTECTANTS (2001), https://www.epa.gov/pesticides/chem_search/reg_actions/pip/bt_brad2/1-overview.pdf ("Tests [of *Bt* corn] have shown no toxicity to mammals . . . and anticipated exposure of farm workers to [Cry1AB and Cry1F] proteins is negligible.").

131. Marvin Vicedo, *The Safety of BT Corn*, FOODRECAP.NET (July 30, 2010), http://www.foodrecap.net/safety/safety-bt-corn/.

132. Nina V. Fedoroff, Opinion, *Engineering Food for All*, N.Y. TIMES (Aug. 19, 2011), https://www.nytimes.com/2011/08/19/opinion/genetically-engineered-food-for-all.html.

133. EUROPEAN COMM'N, EUR 24473 EN, A DECADE OF EU-FUNDED GMO RESEARCH (2001–2010) 16 (2010), *available at* https://op.europa.eu/en/publication-detail/-/publication/d1be9ff9-f3fa-4f3c-86a5-beb0882e0e65.

134. Fed. OFF. CONSUMER PROT. & FOOD SAFETY, *Long-term Effects of Genetically Modified Crops on Health and on the Environment* (2009), https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2006_report_lt-effects_final.pdf; *see also* Fedoroff, *supra* note 132 (noting that the National Academy of Sciences and the British Royal Society have similarly concluded that bioengineered crops are no more dangerous than crops modified by other method).

135. *See Why is Prolonged Exposure to Roundup Weed Killer Potentially Dangerous?*, PRW LAW BLOG (Oct. 11, 2019), https://www.prwlaw.com/why-is-prolonged-exposure-to-roundup-weed-killer-potentially-dangerous ("[T]he consequences of prolonged exposure [to Roundup] can be deadly.").

herbicide that presents risks to human health as would any poisonous pesticide or herbicide, and undergoes regulatory review of those risks.[136] While not genetically-modified itself, genetic-engineering has enabled Roundup's widespread adoption in agriculture. Crops, such as Roundup Ready Soybean and Roundup Ready Corn, have been genetically engineered to withstand Roundup's toxic effects so that Roundup kills the weeds but leaves the crops unharmed.[137] Farmers spraying Roundup allegedly suffer from higher levels of non-Hodgkin's lymphoma caused by their extensive exposure to it.[138] Disagreement exists as to whether Roundup causes cancer. The U.S. EPA, the European Chemicals Agency and other regulators have found it non-carcinogenic.[139] Meanwhile, the World Health Organization has deemed it a "probable carcinogen."[140] Three U.S. juries have found it to cause cancer.[141] Bayer, which acquired Monsanto in 2018, has agreed to pay $9.6 billion to settle existing Roundup lawsuits and has proposed paying an additional $2 billion to cover future lawsuits.[142]

In terms of the potential environmental risks of agricultural biotechnology, the biggest is unintended gene flow. Genetically-enhanced crops might cross-breed with weedy relatives and unwittingly create superweeds.[143] They might also crossbreed with other plants such that some wild plants may no longer exist without the modified traits.[144] As for crops genetically-modified to resist pests, their overall effect on the environment might be positive rather than negative because they largely form an alternative to damaging pesticides and herbicides.[145] According to one study, genetically-modified crops reduced global pesticide use by 286,000 tons in one year alone.[146] Unlike spray-on pesticides, which kill a broad spectrum of insects, genetically-modified plants target specific ones.[147] Herbicide-resistant crops like Roundup require less

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136. *Id.*

137. Erik Kobayashi-Solomon, *Here's the Real Reason Why GMOs are Bad, and Why they May Save Humanity*, FORBES (Feb. 15, 2019, 11:38 AM), www.forbes.com/sidtes/erikkobabyashisolomon/2019/02/15; Jennifer Sass, *ATSDR Report Confirms Glyphosate Cancer Risks*, NRDC EXPERT BLOG (Apr. 11, 2019), https://www.nrdc.org/experts/58uropa58s-sass/atsdr-report-confirms-glyphosate-cancer-risks.

138. *See* Sass, *supra* note 137 ("[T]he ATSDR Report . . . lays out the vast array of scientific evidence linking . . . products like Roundup as they are sold on the shelf to cancer.").

139. Patricia Weiss & Tina Bellon, *Bayer Puts Roundup Future Claims Settlement on Hold*, REUTERS (July 8, 2020, 8:27 AM), https://www.reuters.com/article/legal-us-bayer-litigation/bayer-puts-roundup-future-claims-settlement-on-hold-idUSKBN24921Q.

140. *Id.*

141. *Id.*

142. Sara Randazzo, *Bayer Tries Again to Limit Roundup Liability*, WALL ST. J. (Feb. 3, 2021), https://www.wsj.com/articles/bayer-tries-again-to-limit-roundup-liability.

143. PRINGLE, *supra* note 125, at 171.

144. *Id.* at 174.

145. FOOD & AGRIC. ORG. U.N., THE STATE OF FOOD AND AGRICULTURE (2003–04) 76 (2004) (describing decline in pesticide use as a result of bioengineered crops which has in turn protected farm workers and water supplies and engendered the return of beneficial insects and birds to farmers' fields).

146. Graham Brookes & Peter Barfoot, *Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use*, 9 J. AGROBIOTECHNOLOGY MGMT. & ECON. 139, 277 (2008).

147. Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2184–85 (2004).

tillage, which reduces agriculture's carbon footprint, creates less soil erosion, and decreases water loss.[148]

2. The Cellphone

Extended cellphone use may cause cancer. Cellphones communicate through the transmission of radio signals, a form of non-ionizing electromagnetic radiation.[149] Public health regulators have long known that ionizing radiation, like that emitted by x-ray machines and power lines, can contribute to cancer by breaking the body's molecular bonds and damaging its DNA.[150] The fog of ambiguity centers around whether extended exposure to cellphone's weaker non-ionizing radiation can also have this effect.

Beginning in 1999, research coming out of Sweden indicated a troubling link between brain cancer and cellphone use.[151] Further research deepened this link. In 2011, the Swedish researchers reported a 170% increase in the most common type of brain cancer, astrocytoma glioma, for those who had used cellphones for more than ten years.[152] Those who first used cellphones before the age of twenty had an almost 400% increased risk of glioma.[153] Another group's meta-analysis of the cancer risk of cellphones found an almost doubling of the risk of head tumors, including brain tumors, tumors of the acoustic nerve, and tumors of the salivary gland.[154]

Concern that cellphones might cause brain cancer prompted the World Health Organization International Agency for Research on Cancer (IARC) to

148. Brookes & Barfoot, *supra* note 146, at 83; Michele C. Marra et al., *The Net Benefits, Including Convenience, of Roundup Ready Soybeans: Results from a National Survey*, NSF CTR. FOR INTEGRATED PEST MGMT. (Sept. 2004), https://www.researchgate.net/profile/nicholas_piggott/publication/237717600_the_net_benefits_including_convenience_of_roundup_readyr_soybeans_results_from_a_national_survey/links/5410fc760cf2df04e75d6c58.pdf (reporting marked reduction in tillage by farmers who adopted Roundup Ready soybeans and that such farmers use Roundup Ready largely because of its health advantages to the farmers and to the environment over spray-on herbicides).

149. *Cell Phones and Cancer Risk Fact Sheet*, NAT'L CANCER INST. (Jan. 9, 2019), https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet.

150. *Id*.

151. Lennart Hardell et al., *Use of Cellular Telephones and the Risk for Brain Tumours: A Case Control Study*, 15 INT'L J. ONCOLOGY 113, 113–16 (1999); Lennart Hardell et al., *Case-control study on Cellular and Cordless Telephones and the Risk for Acoustic Neuroma or Meningioma in Patients Diagnosed 2000–2003*, 25 NEUROEPEDEMIOLOGY 120, 120–28 (2005); Lennart Hardell et al., *Case-control study of the Association Between the Use of Cellular and Cordless Telephones and Malignant Brain Tumors Diagnosed Between 2000–2003*, 100 ENV'TL RES. 232, 232–41 (2006); Lennart Hardell et al., *Further Aspects on Cellular and Cordless Telephones and Brain Tumours*, 22 INT'L J. OF ONCOLOGY 399, 399–407 (2003); Lennart Hardell et al., *Tumour Risk Associated with Use of Cellular Telephones or Cordless Desktop Telephones,* 4 WORLD J. SURGICAL ONCOLOGY 74, 74 (2006).

152. Lennart Hardell et al., *Pooled Analysis of Case-Control Studies on Malignant Brain Tumours and the Use of Mobile and Cordless Phones Including Living and Deceased Subjects*, 38 INT'L J. OF ONCOLOGY 1465, 1465–74 (2011).

153. *Id.* For a critique of the Swedish Hardell studies, *see* Anders Ahlbom et al., *Epidemiologic Evidence on Mobile Phones and Tumor Risk: A Review*, 20 EPIDEMIOLOGY 639, 639 (2009). A Finnish study showed 100% increase in the risk for glioma among cellphone users. Ansi Auvinen et al., *Brain Tumors and Salivary Gland Cancers Among Cellular Telephone Users*, 13 EPIDEMIOLOGY 356, 357 (2002).

154. Angelo G. Levis et al., *Mobile Phones and Head Tumours. The Discrepancies in Cause-Effect Relationships in the Epidemiological Studies – How Do They Arise?*, 10 ENV'T. HEALTH 1, 1 (2011); *see also* Michael Kundi, *The Controversy about a Possible Relationship between Mobile Phone Use and Cancer*, 117 ENV'T. HEALTH PERSP. 316, 316 (2009) (discussing cancer risks associated with cellphone use).

launch a major study in 2000 involving thirteen industrialized countries and thousands of participants.[155] It compared the occurrence of two types of brain tumors diagnosed between 2000–2004 in those who used cellphones and those that did not.[156] In May of 2010, it issued its long-awaited report.[157] It found an approximately forty percent increase in the risk for the lethal brain tumor glioma and an approximately fifteen percent increase in risk for the generally non-lethal brain tumor meningioma for those with the highest level of cellphone use.[158] It defined this high-use group as people who used a cellphone for more than ten years, with an average talk time of twenty-seven minutes a day.[159]

A year later, in May of 2011, a Working Group of thirty-one scientists from fourteen countries met at the IARC.[160] The group reviewed hundreds of scientific articles, studies, and individual country reports.[161] It decided to classify cellphone radiation as possibly carcinogenic to humans putting it in the same category as lead, chloroform, and coffee.[162] The Working Group emphasized particular risks for children, noting that children's brains absorb double the radiofrequency energy as those of adults and ten times more energy than adults in the bone marrow of their skulls.[163]

More recently, the U.S. National Toxicology Program (NTP) conducted studies on rats and mice to examine the potential health hazards, including cancer, from exposure to radiofrequency radiation used in 2G and 3G mobile phone technologies.[164] The studies, which spanned ten years and cost $30 million, are considered the most comprehensive, as of 2020, of the effects of radiofrequency exposure in animals.[165] The NTP released its final conclusions in November 2018.[166] Based on the NTP's four categories of evidence that a substance may cause cancer ("clear," "some," "equivocal," and "no" evidence), the study found in male rats: clear evidence of tumors (malignant schwannomas) in the heart; some evidence of tumors (malignant gliomas) in the brain; and some evidence of tumors (pheochromocytomas) in the adrenal glands.[167] The NTP notes that the results in rats are not directly

155. The countries involved were Australia, Canada, Denmark, Finland, France, Germany, Israel, Italy, Japan, New Zealand, Norway, Sweden, and the United Kingdom.

156. Release, International Agency for Research on Cancer, WHO, Press Release No. 200: Interphone Study Reports on Mobile Phone Use and Brain Cancer Risk (May 17, 2010), http://www.iarc.fr/en/media-centre/pr/2010/pdfs/pr200_E.pdf.

157. *Id*.

158. *Id.*

159. *Id*.

160. Press Release, International Agency for Research on Cancer, WHO, Press Release No. 208: IARC Classifies Radiofrequency Electromagnetic Fields as Possibly Carcinogenic to Humans (May 31, 2011), *available at* http://www.iarc.fr/en/media-centre/pr/2011/pdfs/pr208_E.pdf.

161. *Id*.

162. *Id*.

163. *Id.*

164. U.S. Department of Health National Toxicology Program, Cell Phone Radio Frequency Radiation Research Overview (hereinafter NTP Cell Phone Research Overview), *available at* https://ntp.niehs.nih.gov/whatwestudy/topics/cellphones (last visited Apr. 5, 2021).

165. U.S. Department of Health National Toxicology Program, Cell Phone Radio Frequency Radiation Studies (August 2020) (hereinafter NTP Radiation Studies), *available at* https://ntp.niehs.nih.gov (last visited Apr. 5, 2021).

166. *Id*.

167. *Id.*

applicable to humans as the exposure levels and duration exceeded that to which humans may experience from cellphones.[168] However, it states that the studies challenge "the long-held assumption that radio frequency radiation of cellphones is of no concern as long as the energy level is low and does not significantly heat the tissues."[169] In 2019, the NTP released additional findings that exposure to radiofrequency radiation used in 2G and 3G technologies damaged DNA in both rats and mice.[170]

Cellphones pose potential health risks other than cancer. These include damaging sperm,[171] adversely affecting sleep,[172] compromising cognitive functions,[173] and doubling the risk of tinnitus (ringing of the ear).[174]

While the health risks of the cellphone remain uncertain and the subject of scientific disagreement,[175] its environmental hazards do not. Cellphones contain a toxic cocktail of lead, beryllium, arsenic, mercury, antimony, and cadmium.[176] These materials when released into the environment poison plants, animals, and humans.[177] People in industrialized countries discard their cellphones more often than any other electronic device, purchasing a new cellphone every twenty-one to twenty-eight months on average.[178] Discarded cellphones leach. A test

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168. *Id*.

169. *Id.*

170. *Id*.

171. Ashok Agarwal et al., *Effects of Radiofrequency Electromagnetic Waves (RF-EMW) from Cellular Phones on Human Ejaculated Semen: An in Vitro Pilot Study*, 92 FERTILITY & STERILITY 1318, 1318 (2009); I. Fejes et al., *Is There a Relationship Between Cellphone Use and Semen Quality?*, 51 ARCHIVES ANDROLOGY 385, 385 (2005); Geoffry N. De Iuliis et al., *Mobile Phone Radiation Induces Reactive Oxygen Species Production and DNA Damage in Human Spermatozoa* In Vitro, 4 PLOS ONE 1, 1 (2009); A. Otitoloju et al., *Preliminary Study on the Induction of Sperm Head Abnormalities in Mice,* Mus musculus, *Exposed to Radiofrequency Radiations from Global System for Mobile Communication Base Stations*, 84 BULL. ENV'T CONTAMINATION & TOXICOLOGY 51, 51 (2009).

172. Alexander A. Borbély et al., *Pulsed High Frequency Electromagnetic Field Affects Human Sleep and Sleep Electroencephalogram*, 275 NEUROSCIENCE LETTERS 207, 207 (1999); Reto Huber et al., *Electromagnetic Fields, Such as Those From Mobile Phones Alter Regional Cerebral Blood Flow and Sleep and Waking EEG*, 11 J. SLEEP RES. 289, 289 (2002); Reto Huber et al., *Exposure to Pulsed High Frequency Electromagnetic Field During Waking Affects Human Sleep EEG*, 11 NEUROREPORT 3321, 3321 (2000); Reto Huber et al., *Exposure to Pulse-Modulated Radio Frequency Electromagnetic Fields Affects Regional Cerebral Blood Flow*, 21 EUR. J. NEUROSCIENCE 1000, 1000 (2005); Ching-Sui Hung et al., *Mobile Phone 'Talk-Mode' Signal Delays EEG-Determined Sleep Onset*, 421 NEUROSCIENCE LETTERS 82, 82 (2007); *Cellphone Radiation Linked to Insomnia, Confusion, Headaches, Depression,* FOX NEWS (Jan. 20, 2008), http://www.foxnews.com/story/0,2933,324140,00.html. *But see* Christian Haarala, *Pulsed and Continuous Wave Mobile Phone Exposure Over Left Versus Right Hemisphere: Effects on Human Cognitive Function*, 28 BIOELECTROMAGNETICS 289, 289 (2007) (failing to find any effect on sleep or other cognitive function from pulsed RF exposure).

173. Roy Luria et al., *Cognitive Effects of Radiation Emitted By Cellular Phones: the Influence of Exposure Side and Time*, 30 BIOELECTROMAGNETICS 198, 198 (2009).

174. Institute of Environmental Health at the Medical University of Vienna (June 2010).

175. *Mobile Phones and Health: Where Do We Stand*?, EUR. PARL., https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/635598/EPRS_BRI(2019)635598_EN.pdf at 3–7 (hereinafter "*Mobile Phones and Health: Where Do We Stand?*") (last visited Mar. 10, 2021).

176. Nicola J. Templeton, *The Dark Side of Recycling and Reusing Electronics: Is Washington's E-Cycle Program Adequate?,* 7 SEATTLE J. SOC. JUST. 763, 766 (2009); Manasvini Krishna & Pratiksha Kulshrestha, *The Toxic Belt: Perspectives on E-Waste Dumping in Developing Nations*, 15 U.C. DAVIS J. INT'L. POL'Y 71, 73 (2008).

177. Templeton, *supra* note 176, at 766–67.

178. Abigail Ng, *Smartphone Users are Waiting Longer Before Upgrading-Here's Why*, CNBC.COM (May 16, 2019), https://www.cnbc.com/2019/05/17/smartphone-users-are-waiting-longer-before-upgrading-heres-why.html (China-21 months; U.S-24.7 months; France, Germany, England, Italy, Spain-26.2 months).

conducted by the U.S. Environmental Protection Agency, for example, found that all tested cellphones leached hazardous amounts of lead into landfills at levels on average more than seventeen times the federal threshold for hazardous waste.[179]

Industrialized countries often ship disposed cellphones to third world countries for recycling.[180] The largest portion of these have ended up in Agbogbloshie, Ghana or the Chinese village of Guiyu.[181] This has turned Agbogbloshie and Guiyu into the most polluted places on earth.[182] Guiyu residents have blood levels of lead alone that are dozens of times higher than the maximum safety level set by the U.S. Centers for Disease Control.[183] A 2018 ban by China on the direct importation of e-waste has diverted much of this waste to dumps in Hong Kong.[184] The Democratic Republic of the Congo has undergone environmental havoc wrought by the mining of coltan, a relatively rare material used in cellphones.[185] Huge swaths of riverbeds have been cleared of all vegetation and animal life to mine the material.[186] This has decimated, among other things, the world's gorilla population in the Congo.[187]

3. Nanotechnology

Working at the nanoscale and building material atom by atom, as if by Lego bricks, allows human beings to fashion matter with greater precision and complexity than previously fathomed.[188] It enables the construction of new super-materials that are one hundred times stronger than steel, lighter than aluminum and able to transmit a tremendous amount of current or heat without melting.[189] Miniscule nanobots may diagnose and even treat diseases with minimal pain to patients.[190]

Nanotechnology's risks stem from its promise: the smallness of nanoparticles and their high surface area-to-mass ratio. Materials that may be

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179. *The Environmental Costs of Our Cellphones*, TREEHUGGER, http://www.treehugger.com/files/2009/09/cell-phones-changing-the-world-for-good-and-bad-and-how-we-can-use-them.php.

180. Templeton, *supra* note 176, at 763; *see* Bryan Schnedeker, *E-Waste in the U.S. and Internationally* (2011) (unpublished student paper) (on file with author) (discussing issues with electronics waste in developing countries); *see also* Krishna & Kulshrestha, *supra* note 176 (discussing issues with electronics waste in developing countries).

181. Meghan McElligott, *A Framework for Responsible Solar Panel Waste Management in the United States*, 5 ONE J: OIL & GAS, NAT. RES., & ENERGY J., 491 (Jan. 2020).

182. *Id*.

183. U.S. GOV'T. ACCOUNTABILITY OFF., GAO-08-1044, *Electronic Waste: EPA Needs to Better Control Harmful US Exports through Stronger Enforcement and More Comprehensive Regulation* 18 (2008).

184. McElligott, *supra* note 181.

185. DEVRA DAVIS, DISCONNECT: THE TRUTH ABOUT CELL PHONE RADIATION, WHAT THE INDUSTRY HAS DONE TO HIDE IT, AND HOW TO PROTECT YOUR FAMILY 240 (2010).

186. *Id*.

187. According to the United Nations Environmental Program, the number of eastern lowland gorillas in the Congo's national parks has declined by ninety percent; only three thousand gorillas survive. *Id.*

188. Mandel, *supra* note 17, at 1329; Reynolds, *supra* note 17 at 182.

189. Mandel, *supra* note 17, at 1330.

190. Dawn L. Nida et. Al., *Flourescent Nanocrystals for Use in Early Cervical Cancer Detection, 99* GYNECOLOGIC ONCOLOGY S89 (2005)*;* Rick Weiss, *Nanotech Poses Big Unknown to Science*, WASH. POST (Feb. 1, 2004), https://www.washingtonpost.com/archive/politics/2004/02/01/nanotech-poses-big-unknown-to-science/d4c653e5-bb98-4a86-bbba-3bd0de57b017/.

safe on the macroscale could prove toxic at the nanoscale.[191] In general, studies have shown that the smaller the particle and the larger its particle surface area, the greater its potential toxicity.[192] Moreover, due to their small size and large surface area-to-mass ratio, nanoparticles might remain airborne longer than macroparticles as well as avoid filtration.[193] This combination makes them more susceptible to human inhalation.[194] Coupled with their potentially increased toxicity, nanoparticles could prove particularly harmful to the lungs, raising fears that they could become the next asbestos.[195] Just as worrying, inhaled nanoparticles may migrate from the respiratory system to the blood, to other organs and even to the brain as their small size might enable them to dodge the body's internal filters.[196] Nanoparticles incorporated into sunscreens to improve ultraviolet protection could penetrate the skin and prove toxic.[197] In addition, nanoparticles might deform DNA by preventing it from properly replicating, which could lead to genetic mutations that can cause cancer.[198] Nanoparticles may also compromise the body's immune systems.[199]

While nanoparticles hold great potential to sanitize the environment and enable pollution remediation, their small size may involve greater toxicity and may facilitate the spread of the very pollutants to which they bind.[200] Their miniscule size may enable them to linger in the environment longer than large particles. One study found them to damage the brains of fish and to destroy entire populations of water fleas.[201] Another study found that aluminum oxide nanoparticles penetrated crop roots and stunted their growth.[202] Nanomaterials can disintegrate into even smaller particles that might interact with the environment and existing contaminants in unpredictable harmful ways.[203]

B. National and International Regulatory Response

How will domestic regulators as well as the international community address the bevy of uncertain risks presented by these and other major emerging

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191. *Id.*

192. EPA, 100/B–07/001, NANOTECHNOLOGY WHITE PAPER 54 (2007), https://www.epa.gov/sites/production/files/2015-01/documents/nanotechnology_whitepaper.pdf.

193. Mandel, *supra* note 17, at 1342.

194. EPA, *supra* note 192, at 13.

195. Barnaby J. Feder, *Nanotechnology Has Arrived: A Serious Opposition is Forming*, N.Y. TIMES (Aug. 19, 2002), https://www.nytimes.com/2002/08/19/business/new-economy-nanotechnology-has-arrived-a-serious-opposition-is-forming.html.

196. INST. OF MED., IMPLICATIONS OF NANOTECHNOLOGY FOR ENV'T HEALTH RSCH. 34 (2005).

197. Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J. L. MED. & ETHICS 704, 706 (2006).

198. Jessica K. Fender, *The FDA and Nano: Big Problems with Tiny Technology*, 83 CHI. KENT L. REV. 1063, 1068 (2008).

199. *Id.*

200. Thompson, *supra* note 17 at 644–45.

201. Rick Weiss, *Nanoparticles Toxic in Aquatic Habitat, Study Finds*, WASH. POST (Mar., 29, 2004), https://www.washingtonpost.com/archive/politics/2004/03/29/nanoparticles-toxic-in-aquatic-habitat-study-finds/0414b33f-0817-4be7-bdaa-9a7e32318480/.

202. Rick Weiss, *Nanotechnology Regulation Needed, Critics Say*, WASH. POST (Dec. 5, 2005), https://www.washingtonpost.com/archive/politics/2005/12/05/nanotechnology-regulation-needed-critics-say/2c56568f-f11b-4260-b5a9-748b114f697e/.

203. Mandel, *supra* note 17, at 1345.

technologies? Should they adopt a precautionary, better safe than sorry approach, or more of a wait and see approach? The predictive power of patents theory hypothesizes that major emerging technologies characterized by geographic diversity in patent footprints will not trigger an overly restrictive regulatory regime across nations or as a matter of international law. Conversely, major emerging technologies with low diversity in patent footprints, or even more importantly by a technological hegemon, present great risk of igniting a strenuous regulatory regime across nations lacking a meaningful innovative presence in those technologies and as a matter of international law. The discussion below tests the predictive power of patents theory against the three technologies. It illustrates how geographic diversity in patent footprints or lack thereof can help predict the stringency of regulatory response.

1. Agricultural Biotechnology

As unearthed above in Part II, the patent footprints for agricultural biotechnology reveal a lack of geographic diversity and that the United States held an outsized innovative position as compared to other nations. Consistent with the predictive power of patents hypothesis, agricultural biotechnology found itself the early subject of strenuous domestic regulation as well as restrictive international regulation. The United States' outlier presence in the patent office was matched by its outlier position when it came to the regulation of the technology.

The United States first tackled the regulation of biotechnology in 1986 and took the position that the technology was not inherently risky.[204] The United States decided that existing agencies under existing statutes could regulate biotechnology and that regulation and oversight should base itself on assessing the safety of the *products* of biotechnology rather than the *process* by which they were made.[205] Like the United States, the European Union also turned to the regulation of biotechnology in 1986.[206] Unlike the United States, however, the EU decided that that bioengineered crops and foods inherently differed from their conventional counterparts and necessitated new and special regulations.[207]

The EU proceeded to subject agricultural biotechnology to an increasingly strict web of regulations, replete with multilayered approval processes and risk assessments for bioengineered seed, food, and even animal feed.[208] In 1997, it tightened its regulations even further to encompass foods derived from genetically modified grains, even if they no longer contained any genetically-

204. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986) (requiring the review of safety and efficacy of biotechnology products); Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22984-23001 (1992) (describing "scientific considerations that are important in evaluating the safety and nutritional value of foods for consumption by humans or animals").

204. *See, e.g.*, Commission of the European Communities, A Community Framework for the Regulation of Biotechnology, COM (86) 573 Final (1986).

205. *Id.*

206. *See, e.g.*, Commission of the European Communities, A Community Framework for the Regulation of Biotechnology, COM (86) 573 Final (1986).

207. Pollack & Shaffer, *supra* note 11 at 60.

208. *Id.* at 60–61.

modified material, such as processed oils.[209] It also mandated the labeling of all foods[210] and feed[211] containing genetically-modified organisms as well as products derived from them, even if those products lacked any detectable amounts of GM DNA or proteins.[212]

It did not take long for agricultural biotechnology to become the object of international regulatory concern. Developing countries joined by the European Union and many other nations called for the strenuous regulation of biotechnology at the international level. Although not a single genetically modified food had yet to be commercialized, at the seminal 1992 Rio Earth Summit, over one hundred and sixty participating nations adopted provisions of the Convention on Biological Diversity (CBD) that required countries to regulate biotechnology domestically and laid the foundation for a subsequent protocol to regulate it as a matter of international law. [213] Veit Koester of Denmark, one of the three vice-chairmen for the negotiation of the CBD describes how, while other controversial issues in the negotiation of the CBD reflected tensions and ultimate concessions between developing and developed countries, in the case of biosafety and the need for the international regulation of bioengineered organisms, "the confrontation was between the US being against such a system on the one side, and the rest of the world on the other side favoring—at that time at least—that system."[214]

As soon as the CBD entered into force in 1993, its Parties began work[215] on the protocol.[216] The "Biosafety Protocol" was adopted in 2000 and entered into force in 2003.[217] Today, it boasts an impressive one hundred and seventy-three parties.[218] The Protocol spans forty articles and has three annexes.[219] It establishes an advanced informed agreement system for genetically modified organisms intended for release into the environment, such as seeds for planting.[220] It also provides for risk assessments on bulk commodities intended for processing, such as corn for processing into oil.[221] It further provides for the labeling of genetically-modified goods and requires nations to share regulatory

209. Council Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning Novel Foods and Novel Food Ingredients of Jan. 27, 1997, 1997 O.J. (L 43) 1–6.

210. *Id.*

211. Council Regulation (EC) No. 183/2003 on Fixing the Maximum Aid for Concentrated Butter for the 284th Special Invitation to Tender Opened under the Standing Invitation to Tender Provided for in Regulation (EEC) No 429/90 of Jan. 31, 2003, 2003 O.J. (L 27) 6; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *U.S. VS. EU AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD* 5 (2005).

212. *Id.*

213. Convention on Biological Diversity, art. 8(g); art. 19(3), June 5, 1992, 31 I.L.M. 818, 823 (1992). With 196 parties, the CBD is one of the most widely joined treaties ever. As of Aug. 12, 2020, only the United States and the Holy See have not joined.

214. Veit Koester, *The Biodiversity Convention Negotiation Process and Some Comments on the Outcome*, 27/3 ENV'T. POLICY & L. 175, 180 (1997). Mr. Koester subsequently chaired the negotiations of the Biosafety Protocol.

215. COP 1 Decision I/9 (Bahamas, December 9, 1994) (establishing a biosafety experts group).

216. COP 2 Decision II/5 (Jakarta, November 17, 1995) (authorizing a protocol on biosafety).

217. Biosafety Protocol, *supra* note 28.

218. Biosafety Protocol, List of Parties, cbd.org (last visited April 19, 2021).

219. Biosafety Protocol, *supra* note 28.

220. *Id*. at arts. 7–10, 15.

221. *Id*. at art. 11.

decisions about genetically modified organisms through an impressive biosafety clearinghouse.[222] The Parties to the Protocol have held numerous meetings, where they have established, *inter alia*, detailed requirements for the labeling of genetically modified foods.[223] They have even adopted a Supplementary Protocol to the Biosafety Protocol to establish liability and redress for any damage to biodiversity caused by genetically modified organisms.[224]

In contrast to agricultural biotechnology, more nations, in particular European nations, innovated and therefore had a stake in bioengineered pharmaceuticals. While championing the inclusion of human health in the Protocol, the European Union paradoxically sought to exclude bioengineered pharmaceutical goods, products clearly implicating human health, from the Protocol's ambit.[225] Developing countries who produced neither bioengineered food nor bioengineered drugs wanted the Protocol to cover both.[226] In the end, the Protocol expressly excludes bioengineered pharmaceuticals from its regulatory scope.[227]

In a similar vein, the European Union expressly exempted genetically modified food enzymes from its domestic GM approval and labeling requirements. The European Union has one of the largest GM enzyme-producing industries in the world. GM enzymes help produce such goods as cheese and beer. Beer, cheese and other foods produced using GM enzymes do not come with labels in Europe, even though other GM-derived foods do.[228]

As a matter of international law and the domestic laws of approximately ninety nations, the release of genetically modified organisms into the environment requires an environmental risk assessment and government approval before such release.[229] In addition, over eighty countries regulate genetically modified organisms intended solely for food, feed, or processing.[230]

2. The Cellphone

The patent footprints for cellphone technology, which reveal geographic diversity in inventive activity, could not have differed more than the patent

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222. *Id*. at art. 20.

223. *Meetings of the COP-MOP*, CONVENTION ON BIOLOGICAL DIVERSITY, https://bch.cbd.int/protocol/cpb_mopmeetings.shtml (last updated July 27, 2020) (listing the different meetings by the Biosafety Protocol).

224. The Nagoya-Kuala Lumpar Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety art. 1, *adopted* Oct. 16, 2010, 50 I.L.M. 105 [hereinafter Supplementary Protocol].

225. Sabrina Safrin, *The Un-Exceptionalism of U.S. Exceptionalism,* 41 VAND. J. INTL. L. 1307, 1332 (2008).

226. *Id*. at 1344.

227. Biosafety Protocol *supra* note 28, art. 5.

228. POLLACK & SHAFFER, *supra* note 11, at 71.

229. See Second National Report Analyzer, Biosafety Clearing-House, http://bch.cbd.int/database/reports/results (last visited Sept. 25, 2014) (stating that of the 150 out of 163 parties surveyed, eighty-seven report that they have established domestic regulations for the intentional introduction into the environment of genetically modified organisms (question 30), eighty-five report that they have implemented the Protocol's advanced informed agreement system (question 29), and ninety-seven have established a mechanism for conducting risk assessments (question 81); *see also* ROBERT L. PAARLBERG, THE POLITICS OF PRECAUTION: GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES (Steven A. Vosti et. Al. eds., 2001) (explaining the regulation of biotechnology in the developing world).

230. *Id*.

footprints for agricultural biotechnology, which lacked such diversity. As anticipated by the predictive power of patents theory, the international and national response to the regulation of the health and environmental risks of the cellphone could similarly not have been more different. Although numerous studies had begun to point to the serious health risks of holding cellphones to the head, nations have taken few steps to regulate cellphones domestically and no steps to regulate them internationally.[231] The primary international response to the cellphones has been the conduct of studies that lag behind technological advances in cellphones.[232] From a global perspective, the prevailing national and international response has been to facilitate rather than to restrain the technology.

While the European Union had extensively regulated agricultural biotechnology, not until 1999 did it take any action to regulate the cellphone.[233] In July of that year, the European Union Council issued a non-binding recommendation that European member states restrict the sale of cellphones whose bodily absorption rate exceeds 2 Watts per kilogram, averaged over 10 grams of tissue.[234] Despite the soaring use of cellphones, the European Union left the issue of cellphone radiation untouched for a decade. In April of 2009, the European Parliament noted that scientific concern over the safety of cellphone radiation had intensified and that many more people, including children, were using the devices.[235] It refrained, however, from taking further action to protect citizens from potential health risks specifically posed by cellphone radiation.[236] Most European nations have adopted the 1999

231. *See Regulation and Legislation Lag Behind Constantly Evolving Technology*, BLOOMBERG L. (Sept. 27, 2019), https://pro.bloomberglaw.com/regulation-and-legislation-lag-behind-technology (last visited Jan. 26, 2021) (discussing the slowed response of regulation and law to cellphone technology).

232. *Id*.

233. Council Recommendation 1999/519/EC of 12 July 1999 on the Limitation of Exposure of the General Public to Electromagnetic Fields (0 Hz to 300 GHz), 1999 O.J. (L 199) 59 [hereinafter Council Recommendation 1999/519 EC].

234. *Id*. at 65.

235. European Parliament, *European Parliament Resolution of 2 April 2009 on Health Concerns Associated with Electromagnetic Fields*.

236. *Id. and Mobile Phones and Health: Where Do We Stand*?, *supra* note 175, at 8 (reporting that EU last acted on radiation exposure from cellphones in July of 1999 and revealing the lack of cellphone specific regulation since). In April of 2014, the EU Parliament did issue a directive updating its rules on the harmonization of laws pertaining to radio equipment in general, which while not cellphone specific would apply to cellphones. European Parliament and Council Directive 2014/53/EU on the Harmonization of Laws of the Member States Relating to the Making Available on the Market of Radio Equipment and Repealing Directive 1999/5/EC (April 16, 2016). That directive generally intends to ensure the efficient operability of radio devices within the EU free from spectrum interference. It does have a general provision on the health and safety of radio devices which provides that "[w]hen deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market. . . ." Article 10(5), *id.* In addition, in February of 2014 the EU adopted a general directive updating its rules on electrical equipment (which might encompass cellphones). European Parliament and Council Directive 2014/35/EC on the Harmonization of Laws of the Member States Relating to the Making Available on the Market of Electrical Equipment Designed for Use Within Certain Voltage Limits and (Feb. 26, 2014). That directive has a general provision which provides that manufacturers of electrical equipment shall design and manufacture electrical equipment so that persons are "protected against non-electrical dangers of such electrical equipment which are revealed by experience." Annex I, para 2(a).

recommendations.[237] Many other nations have also imposed slight limitations on the SAR emissions of cellphones.[238] No nation, however, requires even the simplest of precautionary safety measures—that cellphones come with headsets, much as cars come with seatbelts.[239]

While the European Union, Australia, Japan, and Korea mandate the labeling of bioengineered foods and the Biosafety Protocol contemplates some labeling,[240] we are not aware of any nation that requires labels on cellphones clearly telling consumers how much SAR the phones emit, and any disclosure requirements were only imposed more than a decade after labeling requirements for GMO foods and the widespread adoption of cellphones.[241] Similarly, few nations require that cellphones or smartphones come with labels warning parents to limit their use by children or to advise that customers use headsets or that men refrain from keeping cellphones in their front pant pockets to avoid damaging sperm.[242] Many cellphones have small print warnings buried in their instruction manuals improbably advising customers to hold the cellphone one inch away from their head and to keep the phone away from their bodies.[243]

The discrepancy between the strict labeling requirements for bioengineered food and the lack of labeling for cellphones is even more perplexing when one

237. *Mobile Phones and Health: Where do We Stand, id.* and Commission of the European Communities, *Report from the Commission on the Application of Council Recommendation of 12 July 1999 (1999/519/EC) on the Limitation of the Exposure of the General Public to Electromagnetic Fields* at 6 (September 1, 2008) (listing countries that have followed the 1999 recommendations).

238. Jorge Contreras & Rohini Lakshane have shown how few Indian nationals have patented technology covering cellphones even in India. Contreras & Lakshane, *supra* note 55. Consistent with the predictive power of patents hypothesis, in 2012, India adopted in its words "one of the most stringent Electro Magnetic Field exposure norms in the world." Id. As of September 1, 2013, only mobile handsets with a revised SAR value of 1.6 w/kg may be manufactured or imported in India, and all new handset designs must comply with this standard as of September 2012. India checks cellphones for compliance. GOVERNMENT OF INDIA DEPARTMENT OF TELECOM, *Ensuring Safety From Radiations: Mobile Towers and Handsets* available at https://dot.gov.in/sites/default/ files/advertisement_0.pdf (last visited Dec.11, 2020). It was also one of the first countries to require disclosure of SAR values at point of sale, *id.*, though these disclosures may be difficult to ascertain, *see infra*.

239. *See, e.g.*, Patrick Holland, *The Galaxy Note 20 Doesn't Come with Headphones and That's a Good Thing*, CNET (Aug. 24, 2020, 2:33 PM), https://www.cnet.com/news/the-galaxy-note-20-ultra-doesnt-come-with-headphones-thats-a-good-thing (mentioning how new cellphone models are not coming with headphones).

240. Biosafety Protocol, *supra* note 28, art. 18.

241. *See* GOV'T OF INDIA DEP'T OF TELECOMM., *supra* note 238 (announcing that in 2012, India required that information on SAR values be available at the point of sale.); *see* Priya Pathak, *Will Your Phone Give You Cancer? Here is How to Check Phone's Radiation aka SAR Value*, INDIA TODAY (Sept. 19, 2017), https://www.indiatoday.in/technology/tech-tips/story/will-your-phone-give-you-cancer-here-is-how-to-check-phones-radiation-aka-sar-value-1048005-2017-09-19 (describing how "today" cellphone users can check their cellphone's SAR on the manufacturer's website or "behind cellphone packaging"); Joel Moskowitz & Larry Junck, *Should Cellphones Have Warning Labels?*, MARKETWATCH (June 11, 2016), www.marketwatch.com/ story/should-cellphones -have-warning labels-2016-06-11 (explaining that Radio Frequency disclosures are "buried in user manuals with tiny print, hidden within smartphones, or made available on the internet." In 2015 Consumer Reports recommended the prominent display of safety information cellphones to no avail).

242. Ronny Linder, *Knesset Backs Bill Requiring Cell Phones to Bear Health Hazard Warning*, HAARETZ (Feb. 29, 2012), https://www.haaretz.com/israel-news/business/1.5199833 (writing that in March of 2012, Israel will pass a law requiring that cellphones sold in Israel bear a warning label that reads "[w]arning-the Health Ministry cautions that heavy use and carrying the device next to the body may increase the risk of cancer, especially among children.").

243. *The Fine Print Warnings Manufacturers State to "Keep a Distance" in the Manual*, PARENTS FOR SAFE TECH., http://www.parentsforsafetechnology.org/cell-phone-and-wireless-fine-print-warnings.html (last visited Jan. 26, 2021); Moskowitz & Junck, *supra* note 241.

considers cost. Labeling bioengineered food necessitates the segregation of the food supply between bioengineered grain and traditional varieties. It is, therefore, quite expensive,[244] potentially increasing costs by twenty-five percent or more.[245] Unlike grains, cellphones are not co-mingled during production or distribution. Cellphone packaging could easily display SAR levels as well as a few recommended safety measures. Both cellphone producers and GMO food producers oppose labels on the ground that labels suggest that their products are unsafe, provide information of little or no use, and will dampen sales.[246] Despite the similar nature of the concerns, many countries require labels on GMO foods but do not require them on cellphones.

If anything, the response by nations and the international community to the cellphone has been to facilitate rather than to regulate it. In the mid-1990's, while the groundwork for the Biosafety Protocol was being laid, the International Telecommunications Union (ITU), a UN specialized agency, sought to facilitate the development of the next generation of cellphones.[247] It did so by indicating which cellphone standards to admit into usage and by encouraging more uniform operating standards around the world.[248]

3. Nanotechnology

Based on nanotechnology's patent footprint, we hypothesize that it will engender a measured regulatory response and a lack of stringent international regulation rather than a robust international legal reaction as generated by agricultural biotechnology. Some have called for nanotechnology regulation based on a forward-leaning precautionary approach;[249] others suggest that governments implement a *sui generis* system, as the EU did with biotechnology, to regulate nanotechnology;[250] still others stress the need for the international regulation of nanotechnology given that nanomaterials cross borders and present risks worldwide.[251]

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244. POLLACK & SHAFFER, *supra* note 11, at 156 (citing Nicholas Kalaitzandonakes, *Cartagena Protocol: A New Trade Barrier*, 29 REGUL. 18–25 (2006)).

245. *Id*. at 337, n. 175.

246. *See* Andrew Pollack, *F.D.A. Hearing Focuses on the Labeling of Genetically Engineered Salmon*, N.Y. TIMES (Sept. 22, 2010), https://www.nytimes.com/2010/09/22/business/ 22salmon.html (discussing unintended consequences of warning labels); *see also* Chloe Albanesius, *CTIA Sues San Francisco over Cellphone Radiation Labeling Law*, PCMAG (July 23, 2010), http://www.pcmag.com/article2/ 0,2817,2366934,00.asp (describing backlash against San Francisco's labeling law); Kendra Srivastava, *Cellphone Radiation Law Delayed Indefinitely in San Francisco*, DAILY CELLULAR PHONES NEWS & CELL PHONES REVS. (May 6, 2011), http://daily-cellphones-news.blogspot.com/2011/05/cell-phone-radiation-law-delayedfor.html (reporting on the subsequent shelving of San Francisco's labeling law).

247. KENNEDY, *supra* note 71 (outlining global standards on 3G use).

248. *Id.*

249. Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENV'T L. REV. 349, 361–67 (2007) (discussing large companies fearing insufficient precautions taken by a start-up company could lead to a nanotechnology scare, resulting in a drop in public confidence and a push for excessive regulation).

250. Gary E. Marchant, Douglas J. Sylvester & Kenneth W. Abbott, 37 J.L. MED. & ETHICS 724, 726 (2009) (cautioning that "[p]roposals for *sui generis* regulation of nanotechnology products" could "create a similar risk of irrational discrimination," as occurred with bioengineered food).

251. Johnson, *supra* note 17.

We believe that nanotechnology's patent footprint signals that none of these more forward-leaning approaches will come to pass. This is not to say that governments will not regulate nanotechnology. They will. However, absent a headline catching disaster involving a nanotechnology product, governments will pursue a measured regulatory approach based on identified or likely risks. Some have cautioned that nanotechnology, if not managed internationally, might follow the path of agricultural biotechnology, creating major international tension and global trade wars.[252] Given nanotechnology's geographically diverse patent footprint, we do not believe that it will generate the kind of friction between nations or trade wars like that engendered by bioengineered food. As was true with the cellphone and in contrast to agricultural biotechnology, patent statistics reveal that numerous nations actively innovate in the nanotechnology space. Many nations therefore likely perceive themselves as having a stake in nanotechnology's future and will not want to hamper that future by encumbering it with strenuous domestic and international regulation as occurred with biotechnology.

Indeed, a review of transnational government approaches to nanotechnology reveals that, as was true with the cellphone, countries appear to be taking similar regulatory approaches to nanotechnology. First, in sharp contrast to agricultural biotechnology and similar to the cellphone, national strategies concerning the regulation of nanotechnology consistently emphasize the potential benefits of nanotechnology when discussing the potential risks. The European Union, for example, "has indicated in no uncertain terms that it wishes to pursue the development of nanotechnology applications, with a view to the realization of important benefits,"[253] while addressing "any negative impact on public health, safety or the environment."[254] The European Commission's first communications on nanotechnology identify nanotechnology "as a core research and development field" and emphasize "the technology's potential for international competition and [European] economic leadership."[255] Australia begins its 2005 report on nanotechnology by stressing the benefits of nanotechnology, including potential gains for the Australian economy, before noting that the government should examine options for a national strategy for nanotechnology that would ensure "an appropriate regulatory framework which safeguards the health and safety of Australians."[256] Australia's 2008 National Nanotechnology Strategy has as its objective to

252. *See* ROBERT FALKNER ET AL., CONSUMER LABELLING OF NANOMATERIALS IN THE EU AND US: CONVERGENCE OR DIVERGENCE? 2 (Chatham House 2009) (warning of potential trade war between EU and US over labeling of nanomaterials); Marchant & Sylvester, *supra* note 26, at 4 (arguing that global harmonization of regulatory regimes for nanotechnology could prevent "the remarkable array" of international problems that occurred with GM foods). *See generally* James D. Thayer, *The SPS Agreement: Can It Regulate Trade in Nanotechnology?*, 4 DUKE L. & TECH. REV. 1 (2005) (discussing the applicability of the WTO's SPS Agreement regulating food safety to nanotechnology.).

253. PELLEY & SANER, *supra* note 26.

254. Commission of the European Communities, *Communication from the Commission, Towards a European Strategy for Nanotechnology*, at 21, COM (2004) 338 final (May 12, 2004).

255. Monika Kuruth, Micahel Nentwich, Torsten Fleischer & Iris Eisenbeger, *Cultures and Strategies in the Regulation of Nanotechnology in Germany, Austira, Switzerland and the European Union*, 8 NANOETHICS 121, 124 (2014) (first communications were in 2004 and 2005).

256. PELLEY & SANER, *supra* note 26.

"capture the potential benefits of nanotechnology while effectively addressing the issues impacting on the successful and responsible development of the technology."[257] The main goal of South Korea's Nanotechnology Initiative is for the country to stand among the top three countries in nanotechnology.[258]

While initial calls for the international regulation of biotechnology came from developing countries,[259] in the case of nanotechnology, the leading developing countries of India and China seek to establish themselves as world leaders in nanotechnology. In contrast to biotechnology, they have refrained from calling for its strenuous regulation either domestically or internationally. Instead, India has focused on investing and encouraging nanotechnology with a view to being at the technology's forefront so as "not to miss the bus" on the technology.[260] China has pursued nanotechnology with vigor and, since 2005, is second only to the United States in nanotechnology investment.[261]

Second, national regulatory approaches first stress the need for information gathering and studies to better understand and identify the risks of nanotechnology. The United States Environmental Protection Agency, which shoulders most of the initial regulatory burden for regulating nanotechnology materials, is illustrative. Its 2007 white paper repeatedly stresses the need to obtain more information on nanomaterials.[262] India has similarly stressed the need to gather information about the risks of nanotechnology.[263]

Third, and importantly, all nations are relying on existing regulatory frameworks, rather than on *sui generis* systems, to regulate nanotechnology.[264] The European Union, for example, is relying on its existing REACH initiative.[265] The U.S. is relying on its current regulatory system.[266]

Fourth, nations are beginning to regulate nanotechnology within their existing systems, but those regulations appear measured rather than having an overarching precautionary approach that would lead to bans on the technology. Moreover, as with the cellphone and in contrast to agricultural biotechnology, the emerging regulatory approaches appear to have more in common with each

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257. AUSTL. OFF. OF NANOTECHNOLOGY, NATIONAL NANOTECHNOLOGY STRATEGY IMPLEMENTATION PLAN (2008).

258. StatNano, *South Korea Plans to Stand Among World's Top 3 States in Nanotechnology*, NBIC+ (Dec. 28, 2013), http://statnano.com/news/45450.

259. Safrin, *supra* note 27.

260. Koen Beuner & Sujuit Bhattacharya, *Emerging Technologies in India: Developments, Debates and Silences about Nanotechnology*, 40 SCI. & PUB. POL'Y 628, 632 (2013).

261. Darryl S.L. Jarvis & Noah Richmond, *Regulation and Governance of Nanotechnology in China: Regulatory Challenges and Effectiveness*, 2 EUR. J.L. & TECH (2011).

262. U.S. EPA, EPA 100/B–07/001, NANOTECHNOLOGY WHITE PAPER (2007), *available* at https://www.epa.gov/sites/production/files/2015-01/documents/nanotechnology_whitepaper.pdf.

263. Beuner & Bhattacharya, *supra* note 260, at 634.

264. Mantovani E., Porcari A., Morrison M. D. & Geertsma R. E., DEVELOPMENTS IN NANOTECHNOLOGIES REGULATION AND STANDARDS 2011 - REPORT OF THE OBSERVATORY NANO (July 2011) (explaining that China, Japan, India, Taiwan, Korea and Thailand [OECD1, OBS1] are not planning specific regulatory actions for nanotechnologies but are looking at European and U.S. approaches as a benchmark for the development of their own).

265. The EU Commission's statements in 2004 and 2005 provided that the EU's existing regulatory framework sufficed to cover nanotechnology and any additional regulation must be embedded into the existing legal framework.

266. *Coordinated Framework*, *supra* note 11.

other rather than not. This reduces the likelihood that nations would press for international rules that exceeded their own level of regulation or seek international rules to shield them from WTO trade sanctions. After all, nations do not assert that the environmental and health regulations taken by other nations violate the WTO's SPS Agreement, when those regulations are similar or identical to their own regulations.[267]

Overall, the European Union has adopted the strictest regulatory approach to nanotechnology, but the United States may not lag far behind. The EU regulates nanotechnology according to its application. As of January 1, 2013, cosmetics containing nanomaterials must be notified to regulators six months prior to their placement on the market.[268] Cosmetics containing nanomaterials must indicate their presence in the list of ingredients with the word "nano."[269] With respect to food, the EU considers nanoscale ingredients, even if previously approved at the macro scale, to be new food additives requiring regulatory approval. In 2014, the FDA issued non-binding guidance for nanotechnology food ingredients and nanotechnology substances that contact food.[270] Like the EU, the FDA has taken the position that food ingredients approved by the FDA at the macro scale do not thereby enjoy approval at the nanoscale. The FDA has made clear that nanomaterials do not enjoy a Generally Recognized as Safe ("GRAS") exclusion.[271] The FDA has not gone as far as the EU in characterizing all nanomaterials as food additives but has informed industry that it should consult with the FDA before putting any nanomaterials in or in contact with food, as those materials cannot be generally recognized as safe.[272] The EU requires nanomaterials in food to be identified in the list of ingredients as "nano."[273] The FDA does not mandate such listing.

In the summer of 2017, the EPA put into place rules that require manufacturers, processors, or importers of nanomaterials to report nanoscale chemical substances in commerce to the EPA, ostensibly for informational purposes.[274] It further requires manufacturers of new nanotech chemical substances to provide information for review by the EPA prior to introducing them into commerce.[275] The EPA has subjected some nanomaterials to regulatory review for safety, such as nanosilver, which acts as an antimicrobial

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267. *See* Thayer, *supra* note 252 (discussing the applicability of the SPS agreement to nanotechnology).

268. Aida Maria Ponce Del Castillo, *The European and Member States' Approaches to Regulating Nanomaterials: Two Levels of Governance*, 7 NANOETHICS 189, 191 (2013).

269. *Id.*

270. Ctr. for Food Safety and Applied Nutrition, *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives*, FDA (June 27, 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging2014).

271. *Id*.

272. *Id.*

273. Del Castillo, *supra* note 268, at 192.

274. *Control of Nanoscale Materials Under the Toxic Substances Control Act*, EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under (last modified Nov. 30, 2017).

275. *Id.*

agent.[276] The EPA has also required the use of personal protective equipment for those working with nanomaterials.[277] The EU has decided not to regulate nanomaterials in electronics.[278]

Other countries are cautiously beginning to regulate nanotechnology, with most adopting a "wait and see" approach. We are aware of no country that has officially called for the international regulation of nanotechnology. In contrast to biotechnology, international organizations are not in the process of laying the foundation for any kind of binding rules to regulate nanotechnology.

V. CONCLUSION

Emerging technologies present the challenge of whether and how to regulate the unknown. Their dangers are often hypothetical, and governments must choose whether to adopt a precautionary, better-safe-than-sorry approach or more of a wait-and-see-approach. The fog of ambiguity creates space for regulatory discretion.

This article has explained and provided some suggestive illustrations of how nations' patent footprints can serve as an early and unexpected predictor of how governments will regulate disruptive technologies in the face of ambiguity both as a matter of domestic and international law. An examination of the patent footprints in agricultural biotechnology revealed that from the earliest days of the technology, the United States exercised a hegemonic innovative presence in the technology. It had the incentive to avoid over-regulating the technology and arguably even to under-regulate it. Other countries, in contrast, had an incentive to pursue international rules that would slow the United States and lacked powerful domestic innovators to push for more moderate standards in their own countries.

Patent footprints for cellphone technology indicate the opposite. Numerous countries were innovating in the technology from its earliest days. They had incentive to see the technology flourish and to resist its strenuous environmental, health and safety regulation in the face of uncertain risk both domestically and internationally.

Based on the geographic diversity in patent footprints for nanotechnology, this article anticipates that governments will continue to pursue a measured level of domestic regulation for the disruptive technology. They will tailor regulations to address specific risks rather than take a more precautionary approach. Even more so, the geographic diversity in nanotechnology foreshadows little appetite on the part of governments to regulate nanotechnology as a matter of international law.

The lessons from these three technologies can be applied to other disruptive technologies in the future. The experience of the United States in the context of agricultural biotechnology should serve as a cautionary tale to China as it emerges as an innovative powerhouse. Just as the United States' patent footprint

276. U.S. EPA, NANOMATERIAL CASE STUDY: NANOSCALE SILVER IN DISINFECTANT SPRAY (2012).

277. *Control of Nanoscale Materials Under the Toxic Substances Control Act*, *supra* note 274.

278. Del Castillo, *supra* note 268.

in agricultural biotechnology signaled its hegemonic innovative presence in that technology, so too an outsized presence by Chinese nationals and institutions in securing patents in a disruptive technology could signal China's potential dominance in that technology. Fear of this potential dominance, particularly if extreme, could trigger an international regulatory response to slow China down and provide time to even the international playing field in that technology.

Patents act as the law's sentinel at the frontier of technology. They provide an early clue as to how other bodies of law will react to a disruptive technology as that technology moves from the law's frontier to its regulatory heartland.