FOOD SAFETY AND SECURITY IN THE *MONSANTO* ERA: PEERING THROUGH THE LENS OF A RIGHTS PARADIGM AGAINST AN ONSLAUGHT OF CORPORATE DOMINATION

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EDITOR'S NOTE

Just prior to going to print with Volume 65, No. 2, the United States Supreme Court, in *Bowman v. Monsanto*, No. 11-796 (May 13, 2013), held that the doctrine of patent exhaustion does not grant a farmer the right to reproduce patented seed without the patent holder's prior authorization. The facts of the case are a key analytical tool in Dr. Ghoshray's essay, below. Although the author does not specifically examine the Court's very recent ruling, he nonetheless examines the policy implications of the predicted ruling and discusses its consequences. For this reason, the Editorial Board has agreed to publish this essay in its current form.

Monsanto should not have to vouchsafe the safety of biotech foods . . . . Our interest is in selling as much of it as possible. Assuring its safety is the F.D.A.'s job. – Phil Angell[1]

I. INTRODUCTION

Since our earliest ancestors' desire for a better hunting weapon to procure food or a better storage facility to avoid spoilage, food safety and security has shaped human social and technological evolution like no other essential element. The need to procure food has shaped our civilization since the first human graced our planet. Food continues to be a pivotal force in humankind's saga of life and death. Yet, despite stratospheric progress in scientific application surrounding food, food security and safety for all citizens continues to elude mankind. Why do some enjoy a feast, while others suffer in a famine? This essay will consider this very disturbing characteristic of human civilization from an American legal perspective.

The critical place of food in the continuation of human existence manifests itself in countless forms of human endeavors that animate mankind's quest for food

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* My scholarship focuses on subsets of International Law, Constitutional Law, Law & Policy, and Human Rights Law, among others. I would like to thank Jennifer Schulke for her assistance in legal research and typing of the manuscript. Also to my beautiful children, Shreyoshi and Sayantan, I owe much for their patience and understanding. I offer much appreciation to the members of the Maine Law Review Editorial Board for their thoughtful suggestions and dedication in the edit process. Finally, as the march of civilization continues to reshape the traditional way of farm life around the world, I dedicate this work to those who have tilled our land, grew our crops and harvested our milk – like the dairy farmers Walter and Martha Schulke of Galva, Iowa.

1. Michael Pollan, *Playing God in the Garden*, N.Y. TIMES, Oct. 25, 1998 (quoting Phil Angell, Monsanto's director of corporate communications), *available at* http://www.nytimes.com/1998/10/25/magazine/playing-god-in-the-garden.html?pagewanted=all&src=pm.

security.[2] To many, within their sociological context, food is also sacred and sublime. Witnessed through the behavioral construct of many cultures, food is revered—even offered to gods and goddesses prior to consumption.[3] Yet, as the false promise of food security ushered in an era of advanced biotechnology applications for food generation, food security has virtually disappeared into the labyrinth of mass corporatization.

Despite unprecedented scientific advancement[4] and technological sophistication,[5] safety and security continues to elude man's quest for food.[6] Even the über-advanced Western civilization suffers from this paradox. This essay attempts to explain this paradox by examining food security and safety in the U.S. through two distinct legal paradigms: biotechnology regulation and intellectual property law.

With this objective in mind, I will make some observations related to food safety and security in the U.S. in Section II. This leads to a discussion of the regulatory landscape of biotechnology seeds in Section III, where I identify the regulatory framework's fragmented status and the cause of inertia within the current system. In Section IV, I make some further observations about the current patent framework's contribution to the evolving menace of transgenic pollution, paving the way for a peek at the microcosm represented by the pending Supreme Court case of *Bowman v. Monsanto* in Section V. In Section VI, I offer commentary on a much less discussed narrative for food law in the U.S.—one which recognizes the linkages between and weaknesses of the two frameworks. I conclude, in Section VII, by noting that at the heart of the food security problem in America is the missing recognition of fundamental human rights for all individuals, which, when taken in conjunction with the existing legal modalities provides a

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2. The story of humankind marches on only because of food. This relationship was formalized by The World Food Summit in 1996. At this Summit, the World Health Organization (WHO) declared that food security is defined as "when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life." *Food Security*, WORLD HEALTH ORG., http://www.who.int/trade/glossary/story028/en/ (last visited Feb. 5, 2013).

3. *See* A CROSSROADS OF FREEDOM: THE 1912 CAMPAIGN SPEECHES OF WOODROW WILSON 356 (John Wells Davidson ed., 1956) ("I have often reflected that there was a very human order in the petitions in our Lord's Prayer. For we pray first of all, 'Give us this day our daily bread,' knowing that it is useless to pray for spiritual graces on an empty stomach . . . ."). Food has been deeply rooted within humankind's religious traditions. As author Devdutt Pattanaik states, "**[**f**]**ood is essential to existence, and to the religious experience as well. Every religion has rituals where food is offered to the worshipped, shared, eaten, or even tabooed." Devdutt Pattanaik, *God-Food for God*, LIFE POSITIVE, http://www.lifepositive.com/Spirit/god/food.asp (last visited Feb. 5, 2013).

4. *See generally FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications* (World Health Org., Meeting Report 2010), *available at* http://www.fao.org/docrep/012/i1434e/i1434e00.pdf; *Improving Access to Agricultural Information*, Food & Agric. Org., 1st Consultation on Agric. Info. Mgmt. Working Document (June 5-7, 2000), *available at* http://www.fao.org/docrep/meeting/x7035e.htm.

5. *See* Derek Heady & Olivier Ecker, *Improving the Measurement of Food Security* (Int'l Food Policy Research Inst., Discussion Paper No. 01225, Nov. 2012), *available at http://www.ifpri.org/sites/default/files/publications/ifpridp01225.pdf.*

6. *See* FOOD & AGRIC. ORG., *The State of Food Insecurity in the World*, at Key Messages (2012) *available at* http://www.fao.org/docrep/016/i3027e/i3027e.pdf. ("[T]he number of people suffering from chronic undernourishment is still unacceptably high, and eradication of hunger remains a major global challenge.").

better interpretation of food law. This illumination can then be used to frame the dialogue surrounding the future of food safety and security in the U.S.

II. THE PARADOX OF FOOD SAFETY AND SECURITY IN THE U.S.

Food security continues to be elusive in underdeveloped countries, where human lives are routinely lost due to food scarcity.[7] Ironically, in the more illuminated West, lives are increasingly put in peril, as the strong undercurrent of political acquiescence emphasizes corporate interest over consumer rights. If the former scenario is an assault on human dignity, the latter must be seen as an affront to mankind's vaunted advancement. Both, however, are fundamental constraints to human development that compel us to consider fundamental rights within food policies.[8] From a human rights paradigm, the right to food must be equated with the right to water and, therefore, can be located within the spectrum of fundamental human right as I have explored elsewhere.[9] This essay does not set to establish a fundamental right to food safety and security; however, an understanding of such rights is important in deconstructing the failed food framework in the U.S. For the time being, this essay sidesteps that issue and instead focuses on the paradox of food safety and security in the West. Within the limited scope of this essay, I simply aim to explore the legal framework that animates the current status of food safety in the U.S.

To trace the paradox within the U.S. food framework, I begin by noting the apparent technological superiority of America's production framework, its well-managed supply chain, and abundance of resources. Yet, the much anticipated boon of a sustainable food security never materialized.[10] This is so for two reasons: first, the burgeoning stress over food safety can be traced to an inadequate regulatory paradigm[11] and, second, the crack in the armory of food security is a product of misapplied identification of intellectual property rights, leading to

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7. The lack of food access and citizens' struggle for survival are evident in many parts of the globe. One example is the Horn of Africa, which faces starvation and famine at staggering rates. *See generally* EUR. COMM'N JOINT RESEARCH CENTRE, *Food Security Bulletin: Special Issue – Horn of Africa* (July 30, 2011), *available at* *http://mars.jrc.ec.europa.eu/mars/content/download/2215/11653/file/MARS_FoodSecurityBulletin_HornOfAfrica_July2011.pdf.*

8. The drive to declare food as a fundamental right has found its way into many significant documents. See Article 25 of the Universal Declaration of Human Rights, which states that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and his family, including food . . . ." Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) art. 25 (Dec. 10, 1948). *See also* Luisa Cruz, *Social Protection and the Right to Food* (Food & Agric. Org., Right to Food Policy Brief No. 3, 2012), *available at* http://www.fao.org/docrep/017/ap601e/ap601e.pdf.

9. *See generally* Saby Ghoshray, *Searching for Human Rights to Water Amidst Corporate Privatization in India:* Hindustan Coca-Cola Pvt. Ltd. v. Perumatty Grama Panchayat, 39 GEO. INT'L ENVTL. L. REV. 643 (2007).

10. A recent USDA report found that in 2011, 14.9% of U.S. households "were food insecure at least some time during the year . . . ." *See* Alisha Coleman-Jensen, et al., *Household Food Security in the United States in 2011*, USDA Report from the Economic Research Serv. (Sept. 2012), *available at* http://www.ers.usda.gov/media/884525/err141.pdf.

11. *See infra* Section II.

inefficiency within the paradigm.[12] This essay interjects further interpretive gloss to deconstruct food security and safety from this dual framework.

By the end of the twentieth century, biotechnology's arrival in the scientific firmament was heralded with great anticipation.[13] Embedded within technology's excitement was the promise of solving the world's food scarcity problem once and for all.[14] That promise remains unfulfilled and this lofty expectation has been replaced with uncertainty on two grounds:[15] (1) the inability of federal food safety regulations to cope with the growing sophistication of biotechnology has allowed genetically modified (GM) crops to flood the food system, and (2) the efficient utilization of intellectual property law's loopholes by technology companies has provided fertile ground to consolidate the food production (seed) industry.[16] In sum, rampant usage of genetic engineering[17] and tinkering with bio-pesticides[18] has

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12. *See infra* Section III.

13. *See GM Food: Head to Head*, BBC NEWS (May 18, 1999), *available at* http://news.bbc.co.uk/2/hi/special_report/1999/02/99/food_under_the_microscope/278490.stm ("The key benefits from this new technology are food security—there is a need to double food supply by 2025 due to population increases, changes in diets and natural disasters brought about by climate change.").

14. *See id.*

15. This essay is prompted by an observation that, in the context of consumers' protection from food-related risks, the required high level of protection of human life, health and the protection of consumers' interests is not adequate in the U.S. Besides a general lack of fair practices in food trade, a micro-level risk analysis in food law and a requisite risk assessment based on independent, objective, and transparent scientific evidence is somewhat lacking. As a result, uncertainty persists in a wide range of sub-sectors within the broader food law framework. Scientific uncertainty continues to exist in identifying and establishing harmful effects on health from genetically engineered food, in application of bio-pesticides in crop and in detecting adulteration of food. *See* Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 442-43 (2007).

16. *See* KRISTINA HUBBARD, FARMER TO FARMER CAMPAIGN ON GENETIC ENG'G, OUT OF HAND: FARMERS FACE THE CONSEQUENCES OF A CONSOLIDATED SEED INDUSTRY 13, 16 (Dec. 2009), *available at* http://farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf.

17. Genetic Engineering (GE) in the context of food production can be defined as crops produced by extracting genes from one species and inserting them into another using recombinant DNA (rDNA) technology. Genetic Engineering is also referred to as the process to develop transgenic or genetically modified organisms (GMO). Besides the gene or DNA fragments for the desired characteristics, genetic engineering inserts "markers" which are used to determine if the desired characteristic was successfully inserted and "promoters" that force such desired characteristics to express their protein(s) at all times. Genetic Engineering is not the same as conventional breeding and has been in vogue for barely a quarter century. Despite FDA scientists determining that GMO crops carry unique risks and should be regulated differently, the regulatory framework has remained behind scientific innovation in such a vitally important area. *See generally Completed Consultations on Bioengineered Foods*, U.S. FOOD & DRUG ADMIN. (last updated Aug. 31, 2012), *available at* http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing; *see also* Michael Bennett Homer, *Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83 (2011).

18. *See* Charles M. Benbrook, *Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years* (Bio Tech Info Net, Technical Paper No. 7, Oct. 2004), *available at* http://organic.insightd.net/reportfiles/Full_first_nine.pdf; *see also* DENNIS T. AVERY, SAVING THE PLANET WITH PESTICIDES AND PLASTICS: THE ENVIRONMENTAL TRIUMPH OF HIGH-YIELD FARMING (2d ed. 2000).

presented the risk of diseases creeping in through transgenic pathways,[19] posing a real danger within the food distribution system.[20]

Inadequate regulation since the 1980s has allowed corporate interests to predominate the consumer food crop in the U.S.[21] An abundance of GM crops began flooding the U.S. food chain without adequately analyzing the long-term effects of consumption of GM crops on human health and the natural environment.[22] The failure to enact procedural safeguards to adequately balance the cost to human and environmental health against the benefit of production efficiency has only inflated corporate profit at the expense of human health and environmental degradation. As a result, the pursuit of food security faces an uncertain future. In the absence of a robust consumer rights framework, both farmers and consumers are heading into a future replete with unsafe and insecure food.[23] Moreover, if the federal regulatory framework continues to rely on arcane federal laws, without incorporating modern research on biotechnology applications' adverse impacts on environmental, ecological, and human health, the threats to food safety will worsen.

These threats are exemplified by the unknown effects of the use of bio-pesticides. There exists a pervasive use of genetic engineering in consumer food crops where the genetic makeup of crop seeds are tinkered with, often times, to eliminate undesirable traits found in nature and at times to make them resistant to bio-pesticides. Such bio-engineered food could cause undesirable, poisonous, and disease-prone impacts as a result of unknown and uncertain chemical compositions, which have been left largely unregulated in the food supply chain.[24] This safety issue is the product of an inadequate and fragmented regulatory framework that is currently overseeing the entire food procurement value chain. Why this regulatory framework suffers from the inertia of moving lockstep with technology's advancement is discussed next.

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19. *See* Ricki M. Helm, *Food Biotechnology: Is This Good Or Bad? Implications To Allergic Diseases*, 90 ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY 90-98 (June 2003), *available at* http://cib.org.br/wp-content/uploads/2011/10/estudos_alimentares05.pdf.

20. *See* Farquhar & Meyer, *supra* note 15.

21. *See* discussion *infra* Section VI.

22. *See generally*, Nina V. Fedoroff, *The Past, Present and Future of Crop Genetic Modification* 27 NEW BIOTECHNOLOGY 461, *available at* http://www.cemus.uu.se/dokument/UAG2011/sdarticle-14.pdf.

23. *See* Mairi Anne Mackenzie, *Industry Reaps GM Bonanza, but We Will Pay*, THE AGE (Apr. 15, 2006), http://www.theage.com.au/news/business/industry-reaps-gm-bonanza-but-we-will-pay/2006/04/14/1144521507502.html (noting how GM technology has given rise to an environment that has not only changed our way of life but has also created a sense of deep-rooted anxiety of over safety and security of food we consume); *see also* Hubbard, *supra* note 16.

24. *See* Miroslaw, Maluszynski et al., *Application Of In Vivo And In Vitro Mutation Techniques For Crop Improvement*, 85 EUPHYTICA, 303 (1995) (commenting on the various genetic engineering techniques developed for crop enhancement that relies on changing mutation rates, the future implications of which are not very clear); *see also* NAT'L RESEARCH COUNCIL, *SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS* (2004) (questioning the adequate safeguard against the astounding development of more than 2300 different crop varieties using radiation based mutation).

III. THE REGULATORY LANDSCAPE FOR BIOTECHNOLOGY SEEDS

The current state of food safety in the U.S. calls for modernization of the federal regulatory framework that oversees the application of biotechnology to crop seeds, especially GM crops. Despite the enactment of the 2011 Food and Safety Modernization Act,[25] the regulation of the U.S. food distribution framework does not depend on direct supervisory authority that stems from an applicable statute. Rather, biotechnology regulation in the U.S. emanates from a manipulative paradigm of regulatory authority based on an innovative interpretation of the Federal Food Drug and Cosmetics Act (FDCA).[26] In its capacity as sole responsible supervisory entity in charge of regulating GM crops, the U.S. Food and Drug Administration (FDA)[27] gains its authority to regulate GM crops through a fragmented approach.

The FDA's lack of expertise in dealing with agricultural, ecological, and environmental concerns is well-documented and discussed widely by reputable scientists in the field. Yet, as a result of creative interpretation of the FDCA, the FDA continues to be the sole regulator of biotechnology-driven food in the U.S.[28] Over the course of more than three decades of regulating relevant biotechnology products in the agricultural arena, the FDA has continually failed to incorporate timely enhancements in law based on technology's advancements. This inability to adequately plug all the regulatory loopholes prevents the agency from addressing the possible adverse consequences that may arise out of the biotechnological interplay between food crops and chemical pesticides.

The above scenario seems to reveal a deeply ingrained inertia within the regulatory framework of biotechnology-driven food crops in the U.S. What is the root cause of such inertia? Looking into the regulatory landscape, the existing flaws within the federal regulatory system for GM crops emanate from a fundamental weakness within the "Coordinated Framework,"—the original backbone of the regulatory structure.[29] At the dawn of the U.S. biotechnology industry in the 1980s, there was a severe lack of applicable statutes relevant to this new technology. This created an ambience of confusion and inadequacy amongst federal regulatory agencies.[30] Confusion and recognition of inadequacy gave way to vulnerability in dealing with new challenges, and thus the agencies sought a

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25. *See* Helena Bottemiller, *The Food Safety Modernization Act – One Year Later*, FOOD SAFETY NEWS, Jan. 20, 2012, http://www.foodsafetynews.com/2012/01/the-food-safety-modernization-act-one-year-later.

26. *See* 21 U.S.C.A. § 393 (Westlaw current through P.L. 112-207).

27. *See* Mike Zelina et al, *The Health Effects of Genetically Engineered Crops on San Luis Obispo County: A Citizen Response to the SLO Health Commission GMO Task Force Report*, (May 2006) *available at* http://www.slocounty.ca.gov/Assets/PH/HealthCommission/GMOTaskForce/Citizen+Response+on+the+Health+Effects+of+GE+Crops.pdf.

28. *See* Homer, *supra* note 17, at 99-101.

29. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

30. *See* THE PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 5 (Sept. 2001), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf.

creative solution in envisioning a collaborative framework.

The idea of a collaborative framework resulted in a regulatory paradigm that was coordinated on paper, but heavily fragmented in its approach due to the overlapping responsibilities with which the various federal regulatory agencies were entrusted. This overlapping jurisdiction was a result of inadequate infrastructures trying to catch up to technological innovations. Unfortunately, attempts to add teeth to the regulatory framework via legislative enactment did not find currency in circulation.

Overlapping jurisdiction created a highly susceptible framework, manifested in each agency's disparate approach to biotechnology issues that the framework had not envisioned at inception.[31] Inadequate knowledge and an incomplete understanding of the scope and future of biotechnology prompted the administration's Office of Science and Technology Policy (OSTP)[32] to formulate the Coordinated Framework in 1986. More than a quarter century later, OSTP continues to be the focal point of supervisory oversight related to biotechnology regulatory scheme for food crops.[33]

Unfortunately, the Coordinated Framework suffers from a mismatch between its stated objective and the various approaches of its member agencies. The Framework continues to be burdened by escalating advancement of technological innovation. This has resulted in sub-optimal oversight. This is due in part to lack of requisite regulatory knowledge and also in part to fragmented oversight that has failed to ensure the safety of biotechnology products. Moreover, the Framework has suffered from implementation disconnects and compliance difficulties even as it attempts to lay the foundation for future decades of policy and regulation.[34]

Thus, despite an abundance of regulatory agencies, the fundamental problem remains unsolved. In its current paradigm, the Coordinated Framework does not distribute regulatory responsibilities based on any exhibited expertise. It does not delegate supervisory responsibility based on any specificity of purpose. The agencies draw regulatory authority based on faulty statutory interpretations that attempt to force-fit new, evolving, and increasingly sophisticated issues into old statutes.[35] This is because the regulatory responsibility belonging to any given regulatory agency is derived from the statutory mandates of that particular agency,[36] and these mandates may not comport with evolving complexities that automatically come with new technology. In this context, decades-old law simply cannot do justice, as it lacks the process-specific regulatory authority. Moreover, within the existing regulatory framework, there exists no singular statute that specifically addresses biotechnology. Similarly, there is no dedicated federal agency that regulates biotechnology.

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31. *Id.*

32. *See* Homer, *supra* note 17, at 100.

33. *See id.* at 100-02.

34. *Id.* at 101-103; *see also* discussion, *infra* Part VI.

35. *See* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 10–11 (2004), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/food_biotech_regulation_0404.pdf.

36. *Id*.

Regulatory agencies' creative manufacturing of authority based on arcane statutes is a reflection of attempts to create the illusion of adequacy and capability of oversight. These agencies' constant struggle to legitimize their oversight functions related to the delegated areas is a strong indication of a deep-rooted weakness within the current regulatory framework. Yet, a closer look reveals how these agencies have prevailed over the years while continuing to do a sub-optimal job of regulating in complex areas within the U.S. food procurement and distribution system. I shall briefly review the functionalities of these agencies and the various legislatives enactments that these agencies utilize in order to justify their oversight functionalities. A look at various agencies and their stated functionalities will also reveal the inadequacies in their oversight.

First, the United States Department of Agriculture (USDA)[37] oversees GM products that could adversely impact agriculture. Yet, the basic responsibility of the USDA has not changed since the original introduction of the coordinated framework.[38] Second, the Environmental Protection Agency (EPA)[39] is in charge of regulating environmental risk. However, the agency has been delegated to measuring and managing adverse impacts of GM crops that are engineered to express natural pesticides. Third, the FDA is tasked with evaluating food safety issues of all biotechnologically-derived and genetically modified products for human consumption.[40] In this regard, the FDA has the responsibility of ensuring food safety for all food products—a responsibility jointly shared with the USDA. While the FDA, through the FDCA,[41] exercises its jurisdiction over biotechnology-based products, including food crops, specificity with respect to biotechnology regulation is conspicuously absent from both the agency task definition and its own interpretation of the Act.

For example, the FDA is authorized to regulate only adulterated foods through Section 342 of the FDCA.[42] The controlling authority of the FDA comes from the statutory provision defining adulterated foods as that which "[b]ears or contains any poisonous or deleterious substance which may render it injurious to health."[43] This language neither compels nor encourages the manufacturers of biotechnology-based food products to research adverse ramifications or potential hazardous implications of genetic modification. Rather, the onus of analyzing any poisonous or deleterious effects is clearly the domain of the agency. By implication, therefore, absent the FDA's intervention, the current regulatory framework does not provide a clear mandate for a biotechnology food producer to be extra vigilant

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37. *See generally* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

38. *Id*. *See also generally* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2174-75 (2004).

39. *See* Statement of Policy, *supra* note 37.

40. *Id*.

41. *See* 21 U.S.C.A. § 393 (Westlaw current through P.L. 112-207).

42. 21 U.S.C.A. § 342(a)(1). "Food" is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." § 321(f). "Food" includes human food, animal feed, pet food, and substances migrating to food from food-contact articles. 21 C.F.R. § 170.3(m) (Westlaw Current through January 31, 2013).

43. 21 U.S.C.A. § 342.

towards consumer food safety.

Scientific research is unanimous in its observation that the specter of injury to human health, environment, and ecology resulting from the recombination, replacement, and substitution of genetic profile[44] is a far more dangerous possibility than that created from the mere presence of poison or pesticide. This is readily perceivable and scientifically supported, yet the FDA regulates GM products within the same framework applicable to the common pesticide.

Another creative way the FDA attempts to regulate biotechnology derived food is by craftily manipulating the statutory meaning of the FDCA term, "food additives."[45] Section 348 regulates food additives by controlling the functional implications of components within food that can render food adulterated.[46] Thus, whenever food contains a component that might be seen as an additive within the meaning of the Act, it automatically triggers FDA oversight.[47] Despite the ability to bring biotechnology products under the FDA's regulatory ambit for federally mandated purposes using this definition, this methodology is inherently flawed as it does not delineate between food additives that are biotechnology-derived and those that are not.

Similarly, from a component definition point of view, FDCA Section 321 defines "food additives" as any substance that is intended for human consumption, may reasonably be expected to become a component of food, or may in any meaningful way affect the characteristic of food.[48] Yet, none of these functionalities, product definitions, or prohibitory mechanisms directly addresses GM food crops. This leaves a huge regulatory gap and a loophole for corporate manipulation as and when needed.

Stepping away from food additives, it is apparent that there remains natural disconnects within the regulatory ambit of the FDA, largely driven by imprecise articulation within the statutory pronouncements of the FDCA. Similarly, vagueness within the FDA's policy statements has presented significant implementation difficulties. Perhaps no other regulatory pronouncement has caused more damage in the field of food safety than the FDA's 1992 policy statement that genetically engineered crops "have been widely recognized and accepted as safe."[49] This policy statement has kept many GE crops outside the regulatory ambit of food additives regulation pursuant to Sections 348 and 321 of the FDCA.[50] Moreover, its broader implications could be devastating for food safety.

To support its 1992 policy statement, the FDA applied a flawed scientific component-level analysis of genetically engineered crops. According to the FDA, genetically engineered crops containing only nucleic acids as the active additional

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44. *See* Homer, *supra* note 17, at 94, 96-99.

45. 21 U.S.C.A. § 321(s).

46. *Id.* § 348(a)(2).

47. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

48. 21 U.S.C.A. § 321(s).

49. *Id.*

50. *See id.* §§ 321(s), 348(a)(2) .

components are kept outside of the agency's regulatory ambit.[51] By extolling the virtues of nucleic acid as essential to human existence, the FDA attempted to allay any safety concerns consumers might have. This misapplied interpretation of human biology is a result of faulty understanding of nucleic acid functionality, regardless of whether nucleic acid is taken in isolation or in collaboration with other elements. The scientific details of this analysis are beyond the scope of this essay, and I shall not belabor this argument further except to note that the FDA's argument is inconsistent with scientific viewpoints that have support in the literature.[52] Following a faulty chain of logic, the FDA thus erroneously transferred the responsibility of food safety to the food producers.[53] Accordingly, it is the producer who must now determine whether a food additive is generally recognized as safe or should be further scrutinized.

It is instructive to note that the FDA applies a much higher standard of review for conventional food sources and supplies, and their adverse implications have been well studied. In this context, it is hard to reason that the implications of biotechnology-derived products are poorly understood. Yet, the FDA continues to evade responsibility, and acquiesces to the wishes and manipulations by the very entities that produce genetically engineered food products and crops. Clearly, by shifting the onus of regulation from the agency to the producer, federal agencies have failed the consumer. The FDA's recommendation of voluntary consultation and review of genetically engineered food products and crops[54] alleviates it from the burdensome responsibility of developing robust standards to regulate GE crops.

This colossal policy failure in the entire regulatory infrastructure has not come by happenstance; rather, it is the culmination of long-standing policy inertia. The lack of a comprehensive regulatory framework for genetically engineered crops poses a dangerous food safety framework for consumers. Absent review and regulation by the federal agencies, consumers cannot be protected from human consumption risks attendant to GE crops. Absent from current regulations and federal reviews of biotechnology-derived products is any acknowledgment of consumer rights,[55] or any consideration of risks related to ecological disaster,[56] environmental degradation,[57] biodiversity contamination,[58] or geological

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51. *See* Statement of Policy, *supra* note 47, at 22,990.

52. *See* Zelina, *supra* note 27.

53. *See* Statement of Policy, *supra* note 47, at 22,991 ("Ultimately, it is the food producer that is responsible for assuring food safety.").

54. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 12 (Jan. 18 2001). *See also* William Freese and David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 BIOTECHNOLOGY & GENETIC ENGINEERING REVS. 299, 299-324 (2004), *available at* http://www.centerforfoodsafety.org/wp-content/uploads/2011/05/BGER-PAPER.pdf.

55. *Id.*

56. *See* Mandel, *supra* note 38, at 2196-98; *see also* John Tuxill, *Nature's Cornucopia: Our Stake in Plant Diversity* (Worldwatch Paper 148, Sept. 1999).

57. *Id.*

58. *20 Questions On Genetically Modified (Gm) Foods*, WORLD HEALTH ORG. question 3(2013), http://www.who.int/foodsafety/publications/biotech/20questions/en; *see also* Rick A. Relyea, *The Impact of Insecticides and Herbicides on the Biodiversity and Productivity of Aquatic Communities*, ECOLOGICAL APPLICATIONS 618-27 (2005), *available at* http://www.whyy.org/91FM/ybyg/relyea2005.pdf.

contamination.[59]

IV. PATENT EXCLUSIVITY AND TRANSGENIC POLLUTION

While the regulatory agencies have been napping at the wheel for the last three decades, biotechnology giants have found fertile ground to extend their control over the U.S. food system. The lack of robust and meaningful biotechnology regulation was the perfect precursor for corporate behemoths like Monsanto to make further inroads into controlling the U.S. food production, which in turn has allowed them to significantly shape both farming practices and consumer habits. In this context, Monsanto's manipulation of U.S. patent law to control use of staple seeds by farmers provides a lens through which to understand the interplay between food security and intellectual property.

Because of the faulty imposition of patent law,[60] and at times flawed interpretation of traditional patent doctrine,[61] food sources in America have become institutionalized and consolidated—and ostensibly hijacked—by a few corporate giants.[62] This has been accomplished through a series of heavy-handed investigations,[63] often followed by unscrupulous settlements[64] and at times through zealous prosecutions by the biotechnology giants. The current patent framework surrounding food crops seems to have only aided corporate interests.[65] The

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59. *See* Katherine K. Donegan & Ramon J. Seidler, *Effects of Transgenic Plants on Soil and Plant Microorganisms*, 3 RECENT RESEARCH & DEVELOPMENTS IN MICROBIOLOGY 415-24 (1999).

60. *See* Richard P. Rozek, *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 3 J. WORLD INTELL. PROP. 889, 889-91 (2000); *see also* Richard P. Rozek & Renee L. Rainey, *Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy*, 4 J. OF WORLD INTELL. PROP. 463, 470-72 (2001).

61. *See* Brief for Amici Curiae Food Safety and Save Our Seeds in Support of Petitioner 20-22, Bowman v. Monsanto Co. No. 11-796 (2013), *available at* http://www.centerforfoodsafety.org/wp-content/uploads/2012/12/CFS_Bowman_Amicus-Brief-12-10-2012_final-version.pdf.

62. *See* DANIEL CHARLES, LORDS OF THE HARVEST 201 (2001); *see also* DAVID MOELLER & MICHAEL SLIGH, FARMERS' GUIDE TO GMOS 8 (2004). This observation is consistent with published data that reveals that, as of 2001, Monsanto was responsible for seed technology for over 90% of world genetically engineered crop production. *See* David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J.L. & TECH. 7 (2003). Additional data indicate that Monsanto has been consistently controlling seed technology at around 90%. *See* CTR. FOR FOOD SAFETY, MONSATO VS. U.S. FARMERS 57 (2005), *available at* http://www.centerforfoodsafety.org/pubs/CFSMOnsantovsFarmerReport1.13.05.pdf .

63. *See* Donald L. Barlett & James B. Steele, *Monsanto's Harvest of Fear*, VANITY FAIR (May 2008), http://www.vanityfair.com/politics/features/2008/05/monsanto200805.

64. Monsanto's unparalleled resources have caused a trail of terror across America's heartland, where the cost to the farmers has continued to devastate families. *See, e.g.*, Monsanto Co. v. Thomason, No. 97-01454 (W.D. La. filed July 23, 1997) (awarding $447,797.05 to Respondents and $222,748.00 to Delta Pine in damages; $279,741.00 in attorney fees and $57,469.13 in costs to Respondents; $82,281.75 in attorney fees and $5,801.00 in costs to Delta Pine; and $75,545.83 for testing fields); *see also Agricultural Giant Battles Small Farmers*, CBS NEWS (Jan. 4, 2011, 10:00AM), http://www.cbsnews.com/8301-18563_162-4048288.html; Greenpeace Austl., *How Monsanto Put This Farmer in Court over GE Seed*, YOUTUBE (Mar. 12, 2009), http://www.youtube.com/watch?v=Us42DZO0NX0.

65. *See* Mike Masnick, *Monsanto Wins Patent Dispute Against Farmer Who Bought Legal Seeds*, TECHDIRT, (Sept. 27, 2011), http://www.techdirt.com/articles/20110927/01185716104/monsanto-wins-patent-dispute-against-farmer-who-bought-legal-seeds.shtml (pointing to the vagueness in patent framework in determining delineation of patentability between the first and second generation of seeds).

resulting ambience of pervasive panic amongst U.S. farmers[66] and an extreme sense of uncertainty among consumers[67] have created a deep apathy and resentment toward corporate food producers among food growers.[68]

Specifically, manipulation of the patent framework by corporate patent holders who have nearly perfected the art of genetic engineering for plant development has resulted in country-wide patent infringement litigations brought by patent holders against farmers who save patented seeds.[69] By falling on the wrong side of the intellectual property paradigm on account of illegitimate application of patented and proprietary technology, seed breeders and farmers have faced significant liability.[70] Thus, biotechnology's promise of the 1980s as the gateway towards a sustainable food system has instead turned into a pervasive headache for both consumers and farmers.[71]

Despite heightened expectations, agricultural biotechnology has neither produced enhanced yields nor eradicated the world hunger. However, like a runaway freight train, once descended upon the scene, commercialization of biotechnology has continued transforming U.S. farming landscape. Extracting exclusivity via its patents, Monsanto's genetically engineered seeds currently dominate U.S. farming practices for various commodity crops. This unbridled commercialization and naked corporate monopoly has a dark side that has not been taken into consideration in granting Monsanto such unprecedented exclusivity.

Commercialization of biotechnology-driven food crops has given rise to mass production and distribution of patented transgenic crops. As evidenced in a variety of commodity crops, some of these transgenic crops can produce insecticides, and a few are capable of withstanding herbicide application. For example, Monsanto has utilized genetic engineering to develop and patent its Roundup Ready (RR)[72] crops, bringing in its wake a burgeoning epidemic of glyphosate-resistant "super weeds."[73] The fallout of this invention has been well-documented through multiple instances of economic harm,[74] fundamental reshaping of choice[75] and lifestyle

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66. *See* Homer, *supra* note 17.

67. *See* Charles W. Schmitt, *Genetically Modified Foods: Breeding Uncertainty*, ENVTL. HEALTH PERSPECTIVES (August 2005), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280366/.

68. *See* Homer, *supra* note 17.

69. *Id.*

70. *See* JAMES MATSON, MINLI TANG, & SARAH WYNN, INTELLECTUAL PROPERTY AND MARKET POWER IN THE SEED INDUSTRY: THE SHIFTING FOUNDATION OF OUR FOOD SYSTEM 11, 14-17 (2012), *available at* http://ssrn.com/abstract=2153098.

71. *See, e.g.*, Geertson Seed Farms v. Johanns, No. C 06-01075, 2007 WL 518624, at *9 (N.D. Cal. Feb. 13, 2007); Ctr. for Food Safety v. Vilsack, No. C 08–00484, 2009 WL 3047227, at *9 (N.D. Cal. Sept. 21, 2009) (highlighting, in a series of litigation, how Monsanto's consolidated market power, heavy-handed use of farmers' investigation, and use of legal frameworks created an environment where farmers and consumers have been confronted with a loss of choice).

72. *See* Saby Ghoshray *Interpreting Myriad: Acquiring Patent Law's Meaning Through Contemporary Jurisprudence and Humanistic Viewpoint of Common Heritage of DNA*, 10 J. MARSHALL REV. INTELL. PROP. L. 508 (2011).

73. *See* Stephen B. Powles, *Gene Amplification Delivers Glyphosate-Resistant Weed Evolution*, 107 PROC. OF THE NAT'L ACAD. OF SCI. 955, 955 (2010).

74. *See supra* Section III.

75. *See* Ghoshray, *supra* note 72.

changes for farmers[76] and consumers,[77] irreversible loss of biodiversity,[78] pervasive contamination within the environment,[79] and irreparable harm to ecology through pollution.[80]

Pollution by transgenic crops is fundamentally different and structurally more dangerous than traditional chemical pollution.[81] With traditional chemical pollution, no gene transfer or fundamental alteration of biologic material takes place.[82] In contrast, some genetically engineered crops propagate pollution via transgenic pathways by triggering widespread contamination as they alter and enhance gene flow from genetically engineered crops to target organic entities and species.[83] Transgenic contamination includes enhanced crop injury, herbicide drift, and proliferation of intractable super weeds. The economic fallout of such contamination comes in the form of cost enhancement to both growers and consumers.[84] Economics aside, there remain other adverse implications. Although fundamental in nature, these negative effects have been neither discussed nor considered in any analysis associated with granting Monsanto-type biotechnology companies exclusive rights to shape U.S. farming practices through the patent framework.

Considering the various fallouts from corporate manipulation of the U.S. patent framework, the paradox of food security becomes even more acute. If there does exist a basic consumer right to food safety and a basic right to retain an agricultural way of life, it is severely threatened by market concentration and consolidation,[85] as well as by market manipulation by corporate domination and monopolization.[86] The time is therefore ripe for a renewed introspection into the interaction between genetic engineering and patent protection.

To better understand the legal framework that is currently being used by corporate giants to prosecute farmers while stripping consumers of their right to food choice, I next explore a prototypical patent prosecution case pending before the U.S. Supreme Court, the outcome of which might reverberate for decades to come.

V. *BOWMAN V. MONSANTO*: A PEEK INTO THE FUTURE

In this Section, I retrace the steps taken by the biotechnology giant Monsanto in using existing provisions within the U.S. patent framework to consolidate its position as a dominant crop seed marketer. Left behind Monsanto's blazing trail of

76. *Id.*

77. *Id.*

78. *See* Schmitt, *supra* note 67.

79. *See* Homer, *supra* note 17.

80. *See* Masnick, *supra* note 65.

81. *See* Michael Hansen, *Genetic Engineering Is Not An Extension of Conventional Plant Breeding: How Genetic Engineering Differs From Conventional Breeding, Hybridization, Wide Crosses and Horizontal Gene Transfer*, CONSUMER POLICY INSTITUTE/CONSUMERS UNION (January 1998), *available at* http://www.consumersunion.org/food/widecpi200.htm.

82. *Id.*

83. *Id.*

84. *See supra* Section III.

85. *See* Hubbard,*supra* note 16 at 1, 11.

86. *Id.* at 13.

corporate glory are stories of broken lives and shattered dreams of ordinary humans. While current legal frameworks emphasize intellectual property rights within the food system, not much energy is devoted to identifying therein fundamental human rights for consumers and non-corporate citizens. This produces palpable imperfections and inherent difficulties for the legal system. Let us take the case of the pending U.S. Supreme Court litigation in *Bowman v. Monsanto*.[87] Despite being billed in some parlance as a plain vanilla patent infringement case, *Bowman* is more than that. *Bowman* typifies the complexities of lives made difficult by a concoction of aggressive patent prosecutions and inadequate regulatory oversight. Moreover, the outcome of *Bowman* will have far-reaching ramifications for not only the future of U.S. farming, but also the future of consumer rights and food security in the U.S., for which the analysis below will proceed in two parts.

A. Prologue: Background, Issues, and Implications of Bowman v. Monsanto

The legal dispute in *Bowman* arrives in part from Monsanto seeking exemption from the long-standing U.S. patent doctrine of "patent exhaustion."[88] The basic premise of law here is that the holder of a patent relinquishes its right to a patent as it relates to the patent holder's bilateral relationship with the buyer. The doctrine thus prevents the patent holder from holding the buyer liable from engaging in acts related to the normal use of the patented product.[89] Monsanto however, has insisted on using a complex doctrinal loophole—the conditional sale exemption.[90] Conditional sale allows the seller of a patented product certain residual rights, even after the sale has been consummated, by proceeding along one or both of the following pathways:[91]

1. Using a contractual arrangement, the seller of the patented product can incorporate a conditional sale provision which can legally bind the buyer into periodic purchase for a designated duration, or, in theory, even until perpetuity. This enables the seller a guaranteed, steady stream of revenue until the conditioned time.

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87. *Bowman v. Monsanto Co.*, 133 S. Ct. 420 (petition for writ of certiorari granted Oct. 5, 2012).

88. *See* Quanta Computer, Inc. v. LG Elecs., 553 U.S. 617, 625 (2008) (stating that "[t]he doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item."); *see also* United States v. Univis Lens Co. Inc., 316 U.S. 241, 251-52 (1942); Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 516 (1917); Adams v. Burke, 84 U.S. 453, 456 (1873); Bloomer v. McQuewan, 55 U.S. 539, 549-50 (1852).

89. *See generally* CTR. FOR FOOD SAFETY, MONSANTO VS. U.S. FARMERS UPDATE 2012 (2012), *available at* http://www.centerforfoodsafety.org/wp-content/uploads/2012/11/Monsanto-v-US-Farmer-2012-Update-final.pdf. *But see, e.g.*, Monsanto Co. v. David, 516 F.3d 1009 (Fed. Cir. 2008); Monsanto Co. v. Ralph, 382 F.3d 1374 (Fed. Cir. 2004); Monsanto Co. v. Strickland, 604 F. Supp. 2d 805 (D.S.C. 2009); Monsanto Co. v. Parr, 545 F. Supp. 2d 836 (N.D. Ind. 2008); Monsanto Co. v. Trantham, 156 F. Supp. 2d 855 (W.D. Tenn. 2001).

90. Brief for Respondents at 10, Bowman v. Monsanto Co., No. 11-796, 2013 WL 179941 (filed Jan. 16, 2013).

91. *See* William LaFuze, Justin Chen, & Lavonne Burke, *The Conditional Sale Doctrine in a Post-*Quanta *World and Its Implications on Modern Licensing Agreements*, 11 J. MARSHALL REV. INTELL. PROP. L. 295, 303-05 (2011) (summarizing the doctrine).

2. The buyer of the patented product is prevented from exercising his or her normal use of the product, on the basis of the stated conditional provision(s) within the contractual agreement.

The difficulty with the conditional sales exception comes from its inherent contradiction with the fundamental premise of the broader patent paradigm. In general, patent law's objective is to avoid absurd results during the course of patent infringement prosecution, or for that matter, during the stipulated life of patent practice. Implicit in the *Bowman* scenario, then, is Monsanto's quest for an assurance that would seem to go against this basic principle, as it attempts to apply the conditional sale exception to the future sale of its patented seed technology in perpetuity.[92] Additionally, Monsanto's argument reveals a carefully crafted strategy of corporate risk management as the company seeks an "end of the run" extension of its contractual arrangement even if the conditional sale exception is exhausted.[93] There is a fundamental divergence between Monsanto's patent argument and traditional patent doctrine, which warrants further exploration.

Historically, the landscape of intellectual property law for agricultural seeds has been animated by the patent exhaustion upon sale doctrine. In principle, any authorized sale should trigger exhaustion of patent rights such that the holder of the patent no longer controls the broader seed market. According to the facts of the case, Bowman purchased GE soybeans on the commodities market—*not* directly from Monsanto, but from a third party vendor—and used the seeds to grow a second generation of crop instead of using them as feed or for biodiesel.[94] These seeds were grown and sold by the third party pursuant to a contract with Monsanto.[95] Under the traditional patent exhaustion principle, upon the consummation of the sale from the third party to Bowman, the patent holder Monsanto would not be conferred any residual control over the use of those seeds, including their subsequent distribution. Monsanto, however, claims that the conditional sale provision in the third party vendor's contract prohibited Bowman from growing a second generation of crop.

Whether or not the outcome of this case should be controlled by the conditional sale loophole within the patent exhaustion doctrine is debatable. Likewise, whether the "normal use" of seeds should exclude their planting to grow a new generation of crop is also subject to a future definitive ruling by the Court. Taking a broader view of the word "use," the concept of normal use could certainly be expanded to not restrict the use of such seeds for farming, as long as farming know-how can be shown to be embedded in the traditional farming knowledge. Thus, the U.S. patent framework is faced with a two-fold difficulty: (1) to identify what constitutes traditional knowledge in this scenario, and (2) to determine the scope of traditional agricultural knowledge, and how this knowledge might impact the limits of normal use for the purpose of delineating exhaustion upon sale from the conditional sale exception.

The complexity of the *Bowman* case comes from the nature of the crops in

92. Brief for Respondent, *supra* note 90, at 12-14.
93. Monsanto Co. v. Bowman, 657 F.3d 1341, 1347 (Fed. Cir. 2011).
94. *Id*. at 1345-46.
95. *Id*.

question. The crops self-replicate in such a way that the second and any subsequent generations are genetically identical to the first generation and, therefore, might legitimately come within the scope of Monsanto's patent. As Monsanto's patent infringement suit proceeded through the district court and the Court of Appeals for the Federal Circuit, the courts' in both instances held that that the patent exhaustion doctrine is not applicable to new copies of the patented product.[96]

If we were to analogize the scenario with an example from the publishing world, the situation is somewhat akin to copyright issues. For example, applying the exhaustion upon sale doctrine, the purchaser of a copyrighted book could resell or distribute the book without infringing on the publisher's copyright. But there exists a major limitation to this exhaustion doctrine. Protection is granted against use of legitimate copy in making subsequent unauthorized copies for profit. Thus, in the farming scenario, growing a second generation of crops from a patented first generation product can be compared with making photocopies of a copyrighted book.

The difficulty in analogizing, however, comes from the fact that photocopying a book is fundamentally different than copying a seed. Books are inanimate objects that cannot self-replicate, whereas second-generation crops may indeed be a product of "sprouting" or self-replication which might very well be considered a traditional farming practice. The question the Supreme Court should consider, then, is whether it is a legitimate farming practice to grow a second generation crop based on patented product of the first generation, and whether this can be considered a normal usage of a product covered under patent exhaustion upon sale. This invites various interesting questions: Does the patented exhaustion doctrine immunize the farmer from legal liability for growing a second and subsequent generations? Or, does the patent holder still retain residual rights to any subsequent generation? Does the self-replicating nature of such seeds confer legitimacy to the farmer's action by embedding within normal usage nature's functionality of self-replication?

In sum, *Bowman v. Monsanto* brings to the surface two very important issues regarding the patent framework: First, the question of whether or not a patent right is exhausted at the point of sale in these biotechnology seeds cases. Second, interrelated with the outcome of this first issue, how the exhaustion doctrine applies to subsequent generations of seeds. Both answers will determine the future of food safety in the U.S. in a significant way.

Relevant to this discussion is the Supreme Court's 2008 ruling in *Quanta Computer, Inc. v. LG Electronics, Inc*.,[97] where the Court noted that "[t]he long standing doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item."[98] This would imply that the condition of use might not affect, implicate, or bind the subsequent purchase sale framework unless the buyers and sellers agree to be bound by a contract during the initial authorized sale. This is a rather plain vanilla framework of ordinary property

96. *See id*.; *see also* Monsanto Co. v. Bowman, 686 F. Supp. 2d 834, 840 (S.D. Ind. 2009).

97. 553 U.S. 617 (2008).

98. *Id.* at 625.

rights law that requires further interpretive gloss.

Here, personal property rights and intellectual property rights do not come in conflict. The issue becomes complicated, not on the exhaustion principle, but rather on the scope of the subsequent use scenarios. Whether exhaustion gives the purchaser the right to use original source materials for generating replicas, or whether the self-replicating functionality immunizes such copy is still subject to the Court's definitive ruling. Whether patent rights in seeds grown by lawful planting is exhausted at the point of authorized sale and thus the self-replicating nature of the invention automatically immunizes subsequent generation as they are already embodied in prior generation, is the key point of contention in the outcome of this patent infringement issue. Clearly, residing at the core of this patent infringement question is the prudent understanding of self-replication, especially in exploring whether self-replication is a legitimate use of the product. The question is what will influence this determination? Will it be the traditional farming knowledge of self-replication of a living organism as part of its natural life cycle, or the linguistic meaning of usage based on how close the various functionalities are from the original usage? No doubt, one of the meanings will certainly shape the final outcome on this very important question of law.

With the complexities arising from the science of self-replication, the lexicographic interpretation of normal usage, and the conundrum generated by these dichotomous concepts animating the longstanding patent exhaustion doctrine, it is clear that the intellectual property framework for biotechnological seeds lacks the interpretive acumen to respond to the innovative twists of technological sophistication. Consequently, selected biotechnology corporations have faced unprecedented consolidation.[99] This has resulted in a significant decrease in seed inventory, which has, in turn, suffocated and stifled scientific research,[100] reduced farmers' independence,[101] and taken away consumers' choice.[102]

We are thus confronted with the telling question: although patent exhaustion has been the mainstay of American patent law for over 150 years,[103] why isn't it applicable to Monsanto and other major biotechnology agriculture giants? The real answer lies in the twisted saga of intertwined policy and politics (an area that is beyond the scope of this essay). Focusing on the legal issue at hand, if the Supreme Court does not retrench the contours of corporate domination, the problems of aggressive prosecution of farmers and gradual weakening of consumer

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99. *See* John Hession, *Biotech Consolidation: Is There Light in the Tunnel?*, MASS HIGH TECH (June 25, 2009), http://www.bizjournals.com/boston/blog/mass-high-tech/2009/06/biotech-consolidation-is-there-light-in.html?page=all.

100. *See* Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research*, N.Y. TIMES (Feb. 19, 2009), http://www.nytimes.com/2009/02/20/business/20crop.html?_r=0.

101. *See* CHARLES BENBROOK, THE ORGANIC CENTER, THE MAGNITUDE AND IMPACTS OF THE BIOTECH AND ORGANIC SEED PRICE PREMIUM 1-3, 6-9 (2009), *available at* https://www.organic-center.org/reportfiles/SeedPricesReport.pdf.

102. *See* Ghoshray, *supra* note 72.

103. The doctrine of patent exhaustion, indicating an initial authorized sale of a patented item exhausts all patent rights to further uses or sales of that item has been one of the mainstays of American patent law. Today called the First Sale Doctrine, it originated in Supreme Court's opinion in the 1853 case of *Bloomer v. McQuewan*, 55 U.S. 539 (1853).

rights will continue to escalate.

As noted elsewhere,[104] most of the farmer prosecutions have been associated with instances of falsehood and impersonation. This has, indeed, changed the farmers' way of life by imposing hurdles along the trajectory of traditional farming practices.[105] For example, a single use restriction via creative patent enforcement through entrapment and confrontation, threat of lawsuits with grievous consequences for saving seeds from prior years, or even chance occurrences in nature via cross pollination or transgenic contamination has increased costs to U.S. farmers and has resulted in economic adversity and restriction of choices to U.S. consumers. Moreover, consumer safety research by independent scientists not affiliated with corporate entities has been stymied due to the unavailability of seeds for analysis.[106] As a result, patent prosecutions to control markets and raise seed prices have unequivocally taken power away from producers and consumers and put it into the hands of a restricted few marketers and seed producers.

While this essay calls for charting a new patent framework, whether via legislative enactment or through a prudent ruling by the Supreme Court, the policy implications of successive administrations must also be examined. Here, the poignant question is how these administrations have allowed consolidated monopolization to continue unchecked. Looking at the comparable landscape of Monsanto's monopoly power in other countries, it is apparent that public interests animate the legal situation in other countries. Although Monsanto enjoys immunity in the U.S. on various fronts as I have highlighted earlier, the reality is fundamentally different in other countries, especially in Argentina,[107] Brazil,[108] and the U.K.,[109] as I have shown elsewhere.[110] When it comes to the U.S. intellectually property framework, the time has come to end special exceptions to corporations.

Even if the Court agrees with the traditional exhaustion upon sale doctrine, it must also address Monsanto's position seeking an end-run around exhaustion. If the Court agrees that the traditional exhaustion upon sale doctrine applies to both the first generation of seeds and its subsequent progenies, the petitioner Bowman would prevail. Recognizing this, the respondent Monsanto included in its filing a pleading for the Court to create for them a new end-run around exhaustion. This new end-run will expand the reach of traditional exhaustion doctrine by allowing

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104. *See* Amicus Brief, *supra* note 61, at 12 ("Respondents devote a staff of 75 with an annual budget of $10 million to their efforts, which are divided into three stages: investigations, attempted coerced settlements, and, if that fails, litigation. They investigate approximately 500 farmers every year. According to interviewed farmers, hired investigators trespass on farmers' property to take photos or crop samples; make threats and engage in harassment; adopt disguises (e.g. pretend to be conducting surveys of seed and chemical purchases); and even engage in entrapment-like activity." (internal citations omitted)).

105. *See* MATSON, TANG, & WYNN *supra* note 76.

106. Because their experiments rely on procuring seed for analysis from farmers, and because corporation closely guard against the procurement of seed for analysis by independent scientists, researchers cannot legally acquire seeds for analysis.

107. *See* Case C-428/08, Monsanto Tech. LLC v. Cefetra BV, 2010 ECJ EUR-Lex LEXIS 1478, ¶¶ 15-32.

108. *See Monsanto Loses in Brazil*, MANAGING INTELLECTUAL PROPERTY (Dec.10, 2012), http://www.managingip.com/Article/3128995/Monsanto-loses-in-Brazil.html?edit=true.

109. *See* Monsanto Tech. LLC v. Cargill Int'l SA & Anor [2007] EWHC [(Pat) (Eng.).

110. *See* Ghoshray, *supra* note 72.

patent holder to avoid patent exhaustion upon sale. However, such an end-run around exhaustion might be difficult to achieve, as the reasoning seems to be in contradiction with both reconfiguring and infringing to 35 U.S.C.A. § 154.[111] It would also be contrary to the *Quanta* opinion by the Supreme Court.[112] However, taking an expanded interpretation of the *Quanta* holding, a contrarian argument could also be asserted. Noting that while *Quanta* is generally recognized a method case,[113] the *Bowman* scenario may be interpreted to fall outside the ambit of a method case by arguing that it is an apparatus case. In other words, by characterizing Monsanto's invention as not falling strictly within the confines of a method patent, argument can be advanced for it being closer to an apparatus patent. This, undoubtedly, would leave the Supreme Court to chart new territory towards developing a more deterministic patent paradigm.

Furthermore, as to the prior discussion on normal usage, the controversy over usage versus generation is a difficult one to reconcile. To resolve the quandary of whether farming with seed is an example of usage or making would invariably depend on interpretation of language. This would lead to yet another paradox of determining whether developing a second generation seed is "making new" or "using to do something." In my view, the answer should resort to basics by determining when patent exhaustion occurred and by utilizing the conventional meaning of ordinary pursuit, following the paradigm presented in *Stenberg v. Carhart*.[114] Relying on more than 10,000 years of history of human civilization, what has been traditionally recognized and understood by mankind as ordinary pursuit should be the controlling authority in determining what constitutes normal usage for the purpose of determining- what activities by the buyer are permitted under sale of a patented product. Implicit in this interpretation is the recognition that patent exhaustion occurs when a purchaser buys a patented item for the purpose of using it in the ordinary pursuit of life. Is making second-generation seed in a self-replicating crop an ordinary pursuit of life, or is it generating newness that is embedded in the original authorized purchase? This is the key question.

On the other hand, not rejecting Monsanto's plea to grant an exception to the conditional sale would be tantamount to conferring upon the dominant corporation an unprecedented market power. The question could also turn on answering whether seed planting by Bowman is an inherent property right. These are complicated questions and require not only using prudent judgment based on tradition and an understanding of historical practices, but also looking beyond tradition and contemplating an uncertain future. This contemplation of the future should strike a balance between corporate right to profit and the consumer's right to food safety and security.

How the Supreme Court decides *Bowman v. Monsanto* could produce devastating consequences for farmers with respect to any future individual attempts

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111. 35 U.S.C.A. § 154 (Westlaw current through P.L. 112-207).

112. Quanta Computer, Inc. v. LG Elecs., 553 U.S. 617 (2008).

113. According to *Quanta*, the sale of an incomplete (but licensed) product that *does not* include all the elements of the invention per the claim, does indeed exhaust the apparatus and method claims of the patent if the incomplete product embodies some portion of the patents. There are some particularized characteristics that guide the definition and meaning of "embedding." *See id.* at 637.

114. 530 U.S. 914, 993 n.9 (2000).

to save seeds purchased from patent owners such as Monsanto. In the event that the doctrine of patent exhaustion is extended to go beyond its traditional confines, or if Monsanto's end use exception is granted, the impact will include more than mere consolidation: excessive corporate concentration could give rise to monopoly-based predatory power held by patent owners. This would both reduce the consumer options and increase costs to various stakeholders. Moreover, these impacts are inconsistent with the basic premise of contract law, which prohibits predatory, unconscionable contracts or contracts entered into without good faith.

B. Bowman v. Monsanto*: Argument and a Cautionary Tale*

The *Bowman* case went before the Supreme Court on February 19, 2013.[115] The decision is not expected by the time this essay sees the light of day. Therefore, this segment of my analysis will refrain from dissecting the merits of the case in absolute terms. Yet I must provide a cautionary tale—a stark reminder of what is at stake. If the Court sees the central questions in *Quanta* and *Bowman* to evolve in different trajectories, it might call for self-replicating biological products in *Bowman* to be treated differently than products in question in *Quanta*. This might shield from patent exhaustion the first sale of self-replicating products. Such a result would imply that, as a biological product moves from one generation to the next, a new set of patent rights is conferred upon the patent holder. This process might continue in perpetuity, thereby permanently foreclosing the patentee's right to the use of seed for planting through the threat of patent infringement. Although this result would impart clarity in dealing with the patentability of self-replicating biological products, it would also be a historic departure from the Court's current trajectory of strengthening the patent exhaustion doctrine. Given the Chief Justice's questioning during the oral argument,[116] which predominantly centered on structuring the patentability argument on corporate monopoly rent-seeking behavior,[117] this could be a likely outcome.

Historically, the Supreme Court has provided much-needed restraint on the

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115. *See* Transcript of Oral Argument, Bowman v. Monsanto Co., 133 S.Ct. 420 (U.S. 2012) (No. 11-796) *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/11-796.pdf.

116. *Id.*

117. *E.g.*, *id.* at 3-4. By "corporate monopoly rent-seeking," I generally draw attention to corporate practices that attempt to extract asymmetric economic benefit by manipulating the existing legal and political landscape. Rent-seeking occurs as the corporate entity extracts additional value by various means, such as imposing barriers to entry to other competitors or developing unilateral ability to fix a higher than normal market price. The term "monopoly rent-seeking" is used to capture the uniqueness of such uncompensated value extraction when the corporate entity enjoys monopoly privileges under the guidance of legal or regulatory framework. Originally introduced in 1967, the concept of "rent-seeking" found traction in 1974 as distinct from the basic profit-seeking behavior of economic agents. *See generally* Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft*, 5 WESTERN ECON. J. 224, 225 (1967) (introducing the idea of "rent-seeking"); Anne O. Krueger, *The Political Economy of the Rent-Seeking Society*, 64 AM. ECON. REV. 291 (1974) (formalizing the same concept). In the current context, I draw a distinction between profit-seeking and rent-seeking behaviors of bio-technology companies, where the former engages in mutually agreeable financial transactions within an efficient market environment, but where the later extracts abnormal profits in a skewed market environment by foreclosing other competitors' meaningful opportunities to compete due to patent exclusivity for a significant period of time.

Federal Circuit's expansionist paradigm, preventing the steady erosion of the patent exhaustion doctrine. This was succinctly made clear in *Quanta*, where the Court proscribed that patent rights should not control the post-sale use or disposition of a product "that substantially embodies a patent."[118] If the central question in *Bowman* is to be evaluated through this prism of *Quanta*, the Court might very well isolate the operational elements of the *Quanta* analysis to provide clarification on the scope and context of "use" and the definition of the "product in question." Since *Quanta* had not conclusively foreclosed the issue of self-replication with the language "that substantially embodies a patent,"[119] the *Bowman* Court may be reluctant to construe such language to describe a self-replicating product. This is especially true because the inherent paradox in structuring patent rights for self-replicating products—such as the RR soybean seeds—leaves uncertain the temporal aspect of patent exhaustion. The following two-pronged inquiry illustrates this paradox.

First, *Quanta* and *Bowman* present two different factual scenarios in the application of the first sale exhaustion doctrine to subsequent generations of the products. This distinction relates to the physical and temporal characteristics of the products in the two cases. The exhaustion issue in *Quanta* dealt with non-biological, inanimate component parts purchased from licensed sources and subsequently assembled to form working products—recognized as a traditional use in the electronics, telecommunications, automotive and aerospace industries.[120] *Bowman*, by contrast, deals with self-replicating biological products. Each successive generation of physical objects (here, seeds) preserves substantial similarity in both its physical and functional characteristics, such that products in subsequent generations may be seen to "embody" the patent itself just as did the first generation. This characteristic might be a pathway through which the *Bowman* Court could preserve the status quo in its formulation of patent exhaustion doctrine but still hold in favor of Monsanto.[121]

Second, within the current contours of patent exhaustion doctrine, self-replicating products present another unique quandary. Currently it is unclear whether the traditional farming practice of using seeds for planting is a prohibited act under patent infringement—akin to copying a CD or a book. By deciding whether farming by harvesting and re-planting seeds is fundamentally distinguishable from "copying" non-biologic, tangible goods like a CD or a book, the *Bowman* Court may be called upon to rename a traditional human act, historically shaped by natural processes. The Court may be forced to re-characterize farming in this way because biotechnological innovation has fundamentally altered the context and confines of the act. Going along this trajectory by the Court will have significant impacts along multiple dimensions in the U.S. food chain, a few of which I shall elaborate below.

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118. *See* Quanta Computer, Inc. v. LG Elecs., 553 U.S. 617, 625 (2008).

119. *Id*.

120. *Id.* at 627-29

121. *Id.* at 637.

First, in response to *Bowman*'s central question, invalidating the patent exhaustion doctrine's applicability to subsequent generation of the seeds in question will undoubtedly weaken the patent exhaustion doctrine. This doctrine has already been eroded through a steady stream of decisions of the Federal Circuit, not all of which find their way into the Supreme Court. Furthermore, if the Court holds that farmers' use of seeds for their foreseeable and natural purposes is illegitimate, it will profoundly impact farmers' traditional way of life—following to its chilling conclusion a trend that began with introduction of biotechnological seeds into U.S. farming practices three decades ago. Any farmer who buys GE seeds will have to re-purchase new seeds for each growing season rather than harvesting and re-planting seeds from the previous generation of crop. The alternative—to eschew GE seeds—is almost certainly illusory. Few farmers will be able to compete in the mass marketplace without using the hardier, pesticide-resistant GE products. Thus, except for farmers catering to the currently-miniscule market for non-GE foods, all U.S. farmers will be forced into Monsanto's preferred paradigm of purchasing new seeds for every generation. This imposed alteration in traditional farming will significantly impact both domestic food security and, more broadly, consumer's food rights, as companies like Monsanto establish a stranglehold on domestic food production.

Second, by conferring the continued right of patent protection on subsequent generations of seeds, the *Bowman* Court might awaken us to a more fundamental quandary in the essential limits of patent rights. As I have shown elsewhere exploring the current patent framework's gradual expansion of scope in the context of biological products,[122] I am once again distressed by the failure of courts and policy makers to contextualize the patentability of biological products within the deeper fundamentals of mankind's common heritage. Who can legally control a product of life?[123] At the core, Monsanto's seed—"roundup ready" or otherwise—is a product of life. Monsanto simply alters it, partially, by replacing one component with a more desirable component. Therefore, the two fundamental questions in *Bowman*—whether patent exhaustion ends at subsequent generations, and whether such exhaustion becomes categorically inapplicable for self-replicating products—leads us to the corollary question: *Who can control a product of life?* We must recognize that, fundamentally, a biotechnology corporation cannot yet *create* a seed—a product of nature—*ex nihilo*. The patent right that is conferred upon Monsanto is to a specific sequence DNA; this is a component part of the seed and is *not* the seed itself. Therefore, conferral upon a corporation by judicial pronouncement of this right to control a product of life will fundamentally alter the ownership of a public resource that must be recognized as

122. *See generally* Saby Ghoshray, *Interpreting Myriad: Acquiring Patent Law's meaning through Contemporary Jurisprudence and Humanistic Viewpoint of Common Heritage of DNA*, 10 J. MARSHALL REV. INTELL. PROP. L. 508, 530-32 (2011) (introducing the concept of common heritage of humanity in discussing the patentability of biological products, which certainly include agricultural seeds).

123. *See* George Kimbrell & Debbie Barker, *Sowing the Seeds of Dissent: Court Takes On Patents on Life Forms*, MERCED SUN-STAR (Feb. 23, 2013), http://www.mercedsunstar.com/2013/02/23/2836351/george-kimbrell-and-debbie-barker.html (noting the authors' introducing the term "product of life"); *see also* Ghoshray, *supra* note 122, at 530-32.

belonging to the public domain.[124] This resource is vital to food safety and human survival. Residing within the characteristics of self-replication is a distinctive feature that makes it a product of life—a uniqueness that must make the "product" distinguishable from products on which corporations can assert right of exclusivity via patent practice and prosecution.[125]

We will miss a fundamental point of asymmetry if we focus only on the doctrinal implication of Vernon Bowman's fight against Monsanto. Corroborated by Mr. Bowman during an interview with the author, his procurement of mixed seeds from the elevator was designed as a risk management practice.[126] When planting a second generation of seeds, a farmer has a much lower chance of growing the crop.[127] If the farmer purchases higher cost seed and fails to produce his desired crop, he loses his investment. Therefore, a typical farmer of mixed crops engages in a natural risk management mechanism by purchasing the licensed product from biotechnological seed companies for his first planting, while relying on a secondary source of mixed seeds (here a grain elevator) for his second planting.[128] The mixed seeds used for the second planting may contain some patented seeds and some non-patented seeds.[129] Generally, not all RR seeds within the mixed variety see the light of day. Only those seeds that germinate into crops might come under the purview of patent infringement.

What makes this situation asymmetric is that if the second planting in question did not grow crop that included Monsanto's patented DNA, Monsanto would almost certainly not have brought the suit for patent infringement. At a functional level, the patent infringement lawsuit in question is partially based on a probabilistic occurrence. Thus, a Supreme Court ruling favorable to Monsanto would deny to any farmer the opportunity to meaningfully manage the economic risk of his or her second crop for fear of accidentally acquiring and growing some patented seeds. Monsanto, meanwhile, would continue to realize, without any risk, the benefits of its seed patents. But the implications are not limited only to farmers who are actively trying to manage risk. Any farmer who even unintentionally grew second-generation patented seeds could come within the expanded scope of patent infringement. This would lead to a truly untenable outcome—an eventuality that did not escape the thoughtful scrutiny of Justice Elena Kagan during the oral argument.[130] Thus, the asymmetry of the framework reveals itself in this dichotomy: a corporation could protect itself by invocation of an expanded, maximalist[131] conception of patentability, but a farmer could be denied the ability

124. Ghoshray, *supra* note 122, at 533-35.

125. *Id.* at 527-29, 531-32.

126. *See infra* Appendix.

127. *Id*.

128. *Id.*; *see also* Petition for Writ of Certiorari 5, Bowman v. Monsanto Co. No. 11-796 (2013).

129. Petition for Writ of Certiorari, *supra* note 128, at 4.

130. *See* Transcript of Oral Argument, *supra* note 115, at 41.

131. The term "maximalist" is used to describe a position/theme in which emphasis is placed on the inclusion of all factors possible associated with the position. By contrast, the term "minimalist" is used to describe a position/theme in which emphasis is placed on eliminating any extra factors and reducing down to only the necessary elements. *See* James Boyle, *Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 97, 107–08 (F. Scott Kieff ed., 2003) (discussing maximalist and minimalist perspectives on gene patenting).

to engage in basic risk management.

It is my hope that in deciding whether to confer upon Monsanto the right to own generations of patented seeds in perpetuity, the venerable Court recognizes patent law's utility and novelty considerations in the self-replication context. Fundamentally, the Court might be prudent in carefully analyzing whether a change in a component within the seed is "markedly different"[132] and significantly novel, as such component level analysis might have a significant bearing on how far the Court expands the patent scope from the first generation to the next generation.[133]

VI. LINKAGES BETWEEN INTELLECTUAL PROPERTY AND REGULATORY FRAMEWORKS

Thus far, I have addressed two legal paradigms, each of which individually and collectively has shaped food safety and security in the U.S. Traditional legal analysis in this arena has typically addressed one of these two legal paradigms, to the exclusion of the other. Deviating from this methodology of focusing on one of the paradigms at a time, this section examines why the linkages between the two frameworks are significant.

This essay searches for answers to the vexing problem of food security and proposes that efforts to resolve the problem of food security lies in the consideration of rights of consumers, farmers, and non-corporate citizens within both paradigms of biotechnology regulation and intellectual property law. The fundamental problem with this approach, however, is that these rights are in contradiction with the established rights of entities like larger seed producers and multinational biotechnology companies.

Both intellectual property law and biotechnology regulation are bound by political processes and cultural frameworks that have allowed the erosion of fundamental rights of consumers. Understanding the linkages between the two legal frameworks starts with recognizing their shared historical strands within the U.S. property rights paradigm. Their shared strands also reflect the stark commonality of the legal system's failure, seen through the myriad lower court cases involving patent infringement by farmers, in which the corporate patent rights have predominantly prevailed over consumer rights or traditional farming rights. In a majority of these cases, the courts, regardless of how unjust and unnatural foreclosing traditional farmers' way of life may be, side with the corporation. Because the current legal process remains constricted within a narrow formalism, it fails to capture corporate consolidation's impact on the broader sociological framework. As a result, the legacy of these judicial opinions continues to foster an atmosphere of abandonment of traditional ways of life and widespread consumer frustration.

This begs the question: must we instead view food security in the U.S. within a fundamental rights narrative? What theoretical framework do we have from which to understand food security from a rights narrative? We are prompted into this inquiry because contemporary food safety and security conversations tend to

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132. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980).

133. *See* Ghoshray, *supra* note 122, at 534-36 (discussing a U.S. District Court's analysis of whether DNA is amenable to patent protection under U.S. law).

originate from either an intellectual property law discussion or a regulatory framework based narrative. Yet, within any narrative of rights, invocation of rights is fluid. Sometimes legal rights are subsumed under broader fundamental rights. Failure to do so has been the fatal flaw of U.S. food rights narrative. Instead, the narrative has been caught within the inconsistencies of diverging strands of rights. Granulating these commingled rights under distinct threads of legal, human, and fundamental doctrines will help in understanding the legal narrative. It is critical in the unfolding story of America's food safety that the rights paradigm is considered. The first step in doing so is to understand the linkages between the intellectual property paradigm and the regulatory framework. The second step is to place the rights of consumers and farmers within a broader spectrum of fundamental rights.

Biotechnology regulation and intellectual property law create certain symmetry within the main legal framework—one without the other simply cannot sustain by itself. To address the impacts of inadequate biotechnology regulation, one must understand what would happen if the patent framework were left with its loopholes. Thus, even if we were to tighten biotechnology regulation, the difficulties that consumers and farmers face would continue due to loopholes within the patent framework. Likewise, even if a robust patent framework were envisioned, the lack of corresponding regulatory enhancement would continue to empower corporations over consumers and farmers. Without making the necessary fixes to the regulatory framework, even the most diligent patent review would fail to solve the problem of food security. Therefore, both the regulation of biotechnology must be tightened and the patent framework must be made robust.

Awareness for food safety in the U.S. must recognize the grave danger of food shortage that lurks beneath the underbelly of a maximalist patent paradigm for biologic products. Thus, if we allow the patent framework to continue its expansionist agenda, the food security in the U.S. might soon find itself hostage to private rights. This is because, manifested in the concentration of the biotechnology seed industry is the shaping effect of an unbridled intellectual property (IP) rights paradigm that some experts view as "biogopolies."[134] As the regulatory mechanism facilitates such market concentration, by conferring monopoly rights through statutory construction, the linkages between a fragmented regulatory framework and an expansionist IP right paradigm become clearer. Although the conferral of statutory monopoly is recognized as an incentive for pursuing creativity in exchange for commercial exploitation, in practical terms, the exclusivity under the IP monopoly has been further accentuated in the absence of a significant regulatory oversight in biotechnology innovations. These combined into a *de facto* mechanism that gave rise to a slew of unethical business practices, including expulsion of competitors and consolidation of market power, among others. This distorted mechanism resulted in a twin-tragedy – the farmers subjugated into exclusive contracts for periodic purchase from seed corporations and the consumers induced into a Hobson's choice of GE food. The emerging threat to the traditional agricultural landscape in the U.S. must be seen through this prism of reality.

Tracing the roadmap towards a future of food safety and security in the U.S.

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134. *See* PETER DRAHOS AND JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY 152-66 (2002).

will require conceptualizing the source of danger. It comes from the linkages between propertization of genetic resources and the biogopoly of proprietary biotechnology. This biogopoly emerged through the combination of patent law and regulatory framework and as such, the linkage has fundamentally altered the original objective of biotechnology – that of achieving food security by enhancing our knowledge to an ultra-restrictive covenant - that of resource concentration via private appropriation of knowledge.[135] By allowing an over-broad patent claim in most biotechnology products, contemporary patent framework has allowed corporations to usurp asymmetric property rights relative to other stakeholders.[136] As the Courts have become the arbiters of patentability, they have continued to lower the patentability threshold for biologic products and living organisms. This has undoubtedly, enabled corporations to secure patents through an expanded conception of "markedly different characteristics."[137] When applied to area of biotechnology seeds, this can only spell disaster for food security, unless the course is reversed by raising the current threshold for patent protection.[138] While the final chapter in the saga of *Bowman v. Monsanto* is yet to be written, the impending decision of the Court must recognize that in its hand lies the recipe to avert a biotechnological anti-commons tragedy.[139]

In an attempt to clarify the relationship between regulatory framework and food safety, I must address the issue of optimal level of federal regulation. Since this area is fraught with many internal inconsistencies, it may have stymied various regulatory efforts in streamlining product assimilation and adoption into the food chain. Often times, a particular innovation either gets fast-tracked into normal use or gets stymied by regulatory hurdles on account of public participation. Therefore, how much public participation must be allowed within the context of federal rulemaking has become one of the thorniest issues in contemporary biotechnological innovation. Moreover, the issue of federalism may have a shaping

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135. *Id*.

136. *See generally* Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U..L. REV. 354 (1999) (expressing apprehension that public domain is increasingly being used for subverting the public's vital interest against in contradiction to Constitutional grants); LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 59 (1999) (arguing that a corporation's broader power in developing technology for the public's use is essentially privatizing public domain); Michael Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998) (describing how socially optimal use of resources have been impeded by over-extension of property rights granted to multiple private entities).

137. *See* Ghoshray, *supra* note 119, at 536-39 (discussing a U.S. District Court's "clear shift to keep products of nature outside the scope of patentability").

138. *See* Human Rights Council, Report of the Special Rapporteur on the Right to Food (Jean Ziegler), A/HRC/7/5 ¶ 44 (Jan. 10, 2008), *available at* http://www2.ohchr.org/english/bodies/hrcouncil/7session/reports.htm (click "E" link for "Report of the Special Rapporteur on the right to food (Jean Ziegler)") ("Although the participation of private sector corporations in food and agriculture sectors may improve efficiency, such concentration of monopoly power entails a danger that will benefit neither small producers nor consumers.").

139. The concept of biotechnology's "anti-commons tragedy" echoes the biomedical anti-commons tragedy. *Cf.* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (May 1, 1998).

affect, which is manifested mostly in giving rise to a delay in granting approval for new products. This brings us to an apparent paradox in biotechnology regulation – finding the right balance between a bottom-up versus a top-down mechanism.

One of the fallouts of the current fragmented approach in biotechnology regulation is the often unnecessary delay associated with the approval process for some products. This elevates the issue of how best to structure an optimum level of public participation in the process, setting up a quintessential point of divergence in law between the public's right to know versus the public's need to know. For example, often times, especially during the initial adoption of newer GE products, an overabundance of public outcry might result in excessively unwanted public participation in the rulemaking process, leading to a perceived information distortion within the regulatory approval process.[140] However, viewing this through the prism of information distortion only tells part of the story. The issue must be viewed in its comprehensiveness, through the balancing struggle between information distortion and information asymmetry. For example, when a biotechnology company attempts to saturate the consumer market with distorted advertisement, drowning along the way advocacy efforts of interest groups, consumer voices must be allowed at least to an optimum extent, to match the corporate efforts. Not doing so will set up for the general consumer a choice between believing a false rationality or a distorted reality. Thus, by allowing public participation in the process, regulatory framework can retain both the sanctity and robustness of the approval process. In this context, how much public participation is to be allowed must be determined through a composite function that balances the information asymmetry introduced by corporate advertisement and information distortion attempted by excessive public participation.

The fragmented nature of regulatory affairs and their imprecise and inconsistent implementation of the approval process creates regulatory impasse within the approval process. The uncertainty introduced by such impasse could evolve in two ways. First, in the absence of a robust trajectory of federal law in a particular area, the states may engage in micro level rule making, which has the potential to unravel by different states developing disproportionate and disjointed regulatory frameworks. This might gravitate in conflict of laws for interstate commerce, calling for the development of a top down approach. Contrarily, however, having a centralized authority within a federal framework supervising a diverging array of intersecting rights and interests may suffer from an inherent drawback. When the confines of law cannot adequately encapsulate local nuances and micro-level specificities that may arise out of the interplay between technology and culture, indeterminacy and incompatibility in implementation may result. This incompatibility and inconsistency calls for developing a bottom-up approach that may suffer from an implementation quagmire in creating indeterminacy in law and making implementation difficult. This sets up a classic conflict in law between the top-down approach and the bottom-up approach.[141]

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140. *See, e.g.*, Lars Noah, *Whatever Happened to the "Frankenfish"? The FDA's Foot Dragging on the Transgenic Salmon*, 65 ME. L. REV. 605 (2013).

141. *See generally* Jeffrey J. Rachlinski, *Bottom-Up versus Top-Down Lawmaking*, 73 U. CHI. L. REV. (2006); Cornell Legal Studies Research Paper No. 05-025, *available at*

Therefore regulatory agencies responsible for food safety in the U.S. must craft a carefully balanced approach by recognizing the inherent limits of federal encapsulation of all possible scenarios within individual localities. The federal approach should proceed on a broader contour that would allow agencies to incorporate a set of touch points with the various sensitive areas where food safety might be at risk, while also recognizing local nuances and cultural sensitivities.

Let us eat and drink; for tomorrow we shall die. – Isaiah 22:13[142]

VII. CONCLUSION

Beneath the glossy veneer of America's food system, there is a silent yet stark reality. This reality manifests itself in many ways: through the documented stories of farmers' plights under biotechnology corporation's seed restrictions, in consumers' inability to identify their genetically modified staples, through transgenic pollution and proliferation of superweeds. Prompted by this realization, this essay embarked on exploring some poignant questions: Is American food security at peril? Has America's legendary food safety been hijacked by unbridled corporatization? Tracing two distinct legal pathways—the regulatory landscape and the intellectual property paradigm—this essay addresses food security and safety along the same thematic lines.

Commenting on the linkages between threats to the food system and the legal paradigms overseeing the system, I contend that, although the concepts are fundamentally distinct, they are also complementary, conveying similar concerns within a broader spectrum. They are also linked in terms of their corresponding supervisory legal frameworks, which leads to two observations. First, threats to food security arise from questionable patent prosecutions of farmers, which are facilitating a broader agenda of corporate hijacking of the intellectual property framework. Second, threats to food safety in the U.S. have been accentuated by lackluster implementation of biotechnology regulations, wherein regulatory authority is derived from arcane statutes and through a fragmented patchwork of federal agencies.

A future safe and secure food supply in the U.S. must be illuminated by two observations from the present. First, the current regulatory framework inadequately deals with the uncertain and complex nuances of biotechnology applications for food crops. Second, loopholes within the current intellectual property framework have allowed leading agriculture biotechnology companies to reshape centuries-old farming practices in the U.S. As an example, by using its leadership position in agricultural biotechnology, Monsanto has been able to both monopolize the market and force both farmers and consumers into making less than optimal choices.

Finally, this essay calls for a reexamination of the traditional discourse on food safety and security in the West. By shifting the conversation into a rights-based narrative, we must first identify the rights that must be part of the conversation. Second, we must place these rights within their identifiable loci. After all, without identifying appropriate rights and how they must evolve, we cannot develop a

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http://ssrn.com/abstract=807685 (discussing the context and scope of the two general methods by means of which democratic legal systems make law).

142. *Isaiah* 22:13 (New King James).

proper construction of such rights. It is high time to recognize the rights of farmers, consumers, and non-corporate citizens within the broader spectrum of fundamental rights. Only then will the inertia within both the regulatory and intellectual property paradigms be disturbed, and only then humans will be empowered to change course from an unbridled pursuit of *eat, drink and be merry* to a tempered pursuit that fosters life, celebration, and more importantly, food and water prosperity for all mankind.

APPENDIX: INTERVIEW WITH MR. VERNON BOWMAN

A. Prologue

Due east of county road 58 in Sandborn, Indiana, almost in the middle of nowhere, sits the farmhouse of Vernon Hugh Bowman (Bowman). Bowman is a soybean farmer. But, he is better known as the petitioner in the Supreme Court case, *Bowman v. Monsanto*, No. 11-796. I conducted an interview[143] with Bowman at his Sandborn farmhouse on March 24, 2013. The work product of the interview included my handwritten notes, and audio and video recordings. Through a prism of Bowman's brief biographical sketch, the interview provides a slice of traditional farm life. In addition, the interview sheds light on aspects of Bowman's litigation with Monsanto by unearthing unexplored vignettes of traditional framing practices that have never been part of the Court's purview. The description below paraphrases our discussion over a period of a long afternoon that continued through early evening.

B. The Farmer: Vernon Bowman

Born in 1937, Bowman never intended to be a soybean farmer. He was also not sure what career path to pursue. Growing up, school was not very interesting to him. He chose the outdoors instead, and undoubtedly, was a freethinking youth that swam against the orthodoxy. He stated that his father "badgered" him to go to college, so he chose Purdue University. He graduated with a degree in Agro Science in 1959 and, in the process, "proved everyone wrong who had doubted whether he would graduate." It is there in West Lafayette, Indiana, that his love of logic and reasoning grew. He had recognized the power of scientific knowledge that he applied later in his farming practices. Still unsure of his future upon graduation, he joined the ROTC and was drafted into the Army. He was stationed at Fort Dix in Trenton, New Jersey, from 1960 through 1962, where he served as a bookkeeper for the Army Officers Corp.

Upon returning from the Army, he worked in the Ohio area as a fertilizer salesman, while dabbling in the real estate business in and around his hometown of Sandborn. During these years, while helping his father and uncle with planting, sowing, and maintaining the farm, Bowman developed his passion for farming and ultimately began farming full-time. At one point, the Bowman family had more than 600 acres of farmland where they planted soybean and wheat.

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143. Interview with Mr. Vernon Hugh Bowman, Sandborn, Indiana (March 24, 2013) (interview on file with the author).

Upon his father's passing, Bowman entered into a joint venture with a fellow farmer. The venture proved disastrous during the 1980s, however, and Bowman "became broke." Forced to sell several plots of land, the remaining 300 acres of land became his sole focus. His current residence on 12676 North Bowman Road is part of this acreage. Bowman is not a rich farmer. He half-jokingly considers himself a "gardener." For several decades, he has made a meager living. He stated that he has no debt, as he has "no expensive habits." So, even after going broke, he was able to keep on farming—albeit, at a scaled-down level.

Bowman never married and has no children. He was extremely close to his mother, who died about seven years ago. He is also very close to his younger sister, Sharon, who resides in Danville, Indiana. Bowman wonders about the future and when he will have to stop farming. When asked if he loses any sleep over the current case before the Supreme Court, he replied, "surprisingly, no. I have not even had a nightmare about it. I am prepared to lose 9-0."

At the end of the interview, Bowman showed me his farmland, equipment, and soybeans. I documented them with photos, and I enjoyed watching his two dogs playing in the snow on the land surrounding the farm. He will be preparing to plant again in April 2013. As I report this, I have made plans to return to witness the planting and do a follow-up interview.

Bowman lives by rigid principles, and possesses a commendable moral contour coupled with the courage of conviction. This is what has driven him to continue his fight against a corporate giant, despite the fact that many of his fellow farmers have either submitted to Monsanto's demands or have been forced to settle rather than litigate. This is what makes Bowman's story compelling. It is a story that must be told.

C. Sample Questions Posed to Bowman, and His Responses

1. What is your view on traditional farming practice?

For years farmers have relied on local seed suppliers. It all changed when Monsanto came along with their Roundup Ready variant. These are costlier, but do produce a good amount of bushels. So, I don't mind paying the premium price for my first planting, and I have been purchasing from Pioneer [a registered seed producer of Monsanto]. But, since nothing is guaranteed for the second planting, we farmers would never pay premium.

2. Why did you buy from the Elevator and not from Pioneer?

Farmers do not want to buy from the dealer for the second planting, as the planting would really be a hit and miss. We all know, Elevators [the local grain silo] seeds are junk seed, because it has no quality control. You never know what you will get, as they contain mixed seeds with different maturities. Think about it. These are commodity seeds—mixed collection from different local growers. I have been buying this junk seed for my second planting, which I know has a lower chance of crop generation due to the timing. This is a typical practice by local farmers. Don't rely on me. Go, ask any farmer. Even ask the Huey Elevator folks that sold me the seeds for my second planting.

3. Do you think you have made a mistake? Do you think you have infringed on Monsanto's patent?

If I am wrong, I am okay with someone telling me I am wrong. I had even gone to several farmers meetings and asked about what I was doing with the elevator grain. No one had said that there was any problem. So, here in this farming community, buying seed from the Elevator for the second planting is a common practice – farmers have been doing it for a long time. When two investigators from Monsanto came to speak with me towards the end of 2006, I did not hide anything. I told them what I was doing. Even the Elevator should have informed me and all the farmers.

I see two things are happening here. First, Monsanto is forcing their patent on me. Second, by allowing the Elevators to sell seeds they have already abandoned their patent claim. In my mind, the very moment Monsanto allowed the Elevator to mix seeds with no accountability, they have given up on their patent. How can they sue me for infringement? So, instead of suing me, they should sue the Elevator first. But, they know, they may not stand on solid ground, as they have already abandoned their patent rights.

So, I don't think, I had violated any patent right. I am still baffled, that no one has been able to explain this in clear terms. You should not be able to reclaim your patent once you have abandoned it.

4. *Why don't farmers rush to the Elevator to purchase seeds? The Oral arguments in the Supreme Court seem to suggest that this might be a real possibility if they let you get off completely free.*

Farmers don't use elevator seed all the time, because it is junk seed. It is a cheaper for us, but it is of mixed variety, so you are not sure of its quality. You are not even sure of their relative maturities, so you can't even plan properly. So, if you are a legitimate farmer, you don't want to use such seeds for your primary planting. It is a guessing game, as you don't know whether you will get any crop at all. Even if you get some, you would not know what value would be there. Also, you spray with weed control because you don't know what the mixed elevator seeds have in them. So, why should we give the big company premium price for something we are not even sure will sprout?

5. *Can you please take me through the timeline of your seed planting and the differences between the types of seeds in question again, as it seems there was confusion on these issues at oral argument.*

Over the years, I have purchased high quality soybean seeds from Monsanto's approved seed producer, Pioneer. These are costlier seeds, and generally expected to produce a quality crop that farmers can sale. Typically, these seeds are planted in April as the first crop, and subsequently harvested around October. This is considered the first and the best crop.

Some of us farmers would try to get a second crop. They would be planted approximately a month later. Farmers who plant this second crop know that there is a very high chance it would be a failure, as they would produce minimal to no crop worth selling. Because this crop is planted later in the season, soil quality, rain, temperature, and other factors make this a very risky crop to plant. Also, once you buy it from the Elevator, you have no idea of [its] maturity, as they have different maturities mixed in them. So, how do I manage my risk of crop failure? I chose to purchase a much less quality seed, because it is cheaper. The cheapest seed to choose for this second planting is the Elevator seed. Ask any farmer you

would like. They will tell you that we are completely clueless as to what will be produced from these seeds. They could easily be used for cattle feed. That's why these throwaway seeds are called junk seeds and they are cheaper.

6. Why do you think buying junk seeds for planting is not patent infringement?

I have been doing this for decades now. See, junk seeds have no fixed identity. It is not possible to separate them once they are mixed in. You cannot count and trace their biological lineage and pay companies accordingly. You would not know whether they came from Monsanto or from the farmer down the road. So, I felt there were no patents in it to worry about. So, I did not think the Elevator seeds had restrictions in it.

D. Author's Commentary

What brings Bowman to the highest Court in the land? Is he in violation of Monsanto's patent right by practicing what he has done over several decades? The answers reside at the grey area intersecting the legal contour with the trajectory of justice. In examining whether Bowman has infringed on anyone's patent rights, we must attempt to conceptualize two other related rights. The first involves the farmer's right to protect his livelihood by employing an adequate risk management practice. The second involves a community's right to practice and protect a traditional way of life. After all, if a corporation is allowed various protections within the law, why isn't an individual farmer allowed such extended legal protection? Yet, often times, in its inability to extricate itself from the narrow formalism of property rights, law's evolution ignores the consequentialism of justice. Whether or not Bowman has violated anyone's right is a complex question that must be evaluated within the context of the "rights intersection."

Finally, *Bowman v. Monsanto* is emblematic of a much deeper problem with the contemporary patent paradigm—one that is out of touch with the public justice construct in emerging economies.[144] Here, there are many issues to consider. Why didn't Monsanto go after the Elevator that mixed in Monsanto's RR seeds with the other variety seeds? Could there be a legitimate argument indexed at Monsanto's patent abandonment in their relationship with the Elevator, as Monsanto never prevented the Elevator from comingling their RR seed with the other seeds? Should patent law be so blind to justice that its strict property rights based invocation might permanently transform traditional ways of life? Will the Court consider these issues before rendering its verdict?

E. Epilogue

We shook hands. I thanked Bowman for his time. He was gracious, polite, but in a hurry to get to the only open diner in town before it closed. It was several miles away. He wanted a sandwich.

As I pulled away, I scanned Bowman's remaining acres, the rusting farm equipment, and the isolation in the midst of the Midwest prairie. I was alarmed by

144 *See, e.g.*, Novartis Ag v. Union of India, et. al., Nos. 2706-2716 OF 2013 (SLP(C) Nos. 20539-20549 OF 2009) (2013) *available at* http://supremecourtofindia.nic.in/outtoday/patent.pdf (decision of India's Supreme Court, denying Novartis' appeal against the decision to refuse patent protection for its anticancer drug, Glivec)

the stark reality of an American past slowly waning into the future of corporatized farming—a future that is obliterating the last vestiges of the American farmer.