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Food Patents: The Unintended Consequences

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FOOD PATENTS: THE UNINTENDED CONSEQUENCES

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I . INTRODUCTION

All of intellectual property (IP) encourages innovation, at least in part. Trademark protection promotes the creation and use of innovative shorthand identifiers for products and services.[1] Copyright encourages creative expression in words, symbols, and (today) multimedia productions.[2] Trade-secrets promote innovation by protecting investment in (usually productive) secrets from industrial espionage and other "improper means" of acquisition.[3] And patents protect

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1. *See* Qualitex Co. v. Jacobson Prods. Co., Inc., 514 U.S. 159, 163 (1995) ("In principle, trademark law, by preventing others from copying a source-identifying mark, 'reduce[s] the customer's costs of shopping and making purchasing decisions.'") (quotation omitted).

2. *See* Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 349 (1991) (to "promote the Progress of Science," . . . "copyright assures authors the right to their original expression . . . .").

3. Trade-secret protection also promotes commercial ethics and discourages unfair competition. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) ("The maintenance of

technological and design innovations, nearly completely, from copying or unauthorized use during the patent's term.[4]

All forms of IP can apply to food, or at least to recipes and packaging for food. But patents are the most important form for food because they relate most closely to food's nutritive and other properties. Trademarks protect only the name;[5] cake by any other name would taste as sweet. Copyright can protect recipes and packaging, but not the product of the recipe or the contents of the package.[6] Trade-secrets can protect products and processes; but as our Supreme Court has noted, "[w]here patent law acts as a barrier, trade secret law functions relatively as a sieve."[7] Legal protection for secrets does not prevent others from making, using or selling the same things, for example, when those secrets are derived from independent development or reverse engineering. Patents do.

Only patents provide complete legal protection for the nature, composition, quality, character and ingredients of things that we eat or drink.[8] In so doing, patents provide massive financial incentives for innovation in these things. They push us humans to make and sell—and therefore to eat and drink—things that we have never eaten or drunk before.

This short paper explores the unintended consequences of this strong economic incentive. The underlying assumptions of patent law and its economic incentive are that innovation is good, and newer is better. But is that always so? Science and history suggest maybe not, for some very fundamental reasons. And there are reasons to believe that the risks of unintended consequences of innovation in food may be more hazardous than those in other fields of innovation.

II. WHY FOOD IS DIFFERENT

At the outset, I ought to define what I mean by "food patents" or "patents on food." For purposes of this paper, I define the term quite broadly. It includes any patent on technology that affects the growing,

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standards of commercial ethics and the encouragement of invention are the broadly stated policies behind trade secret law.").

4. 35 U.S.C. § 271(a) (2012) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

5. *Qualitex*, 514 U.S. at 163.

6. *Feist*, 499 U.S. at 349.

7. *Kewanee Oil*, 416 U.S. at 490.

8. 35 U.S.C. § 101 (2012).

production, processing, composition, packaging, storage, and/or consumption of food or drink. In other words, if a patent covers or affects what we imbibe or ingest, it is a "food patent."

Why do I suspect that food patents, so broadly defined, are different from other types of patents in other industries? There are four reasons: one from economics, two from basic science, and one from agronomy.

A. Economics

The economic reason is that food is a low-profit-margin business.[9] Why? Food is necessary for life. So everyone buys food. As a result, businesses involved in producing and distributing food have more competition than virtually any others.

According to classical economics, this fierce competition drives prices down toward marginal cost and drives profit down toward the minimum that lets business survive.[10] The result? Profit margins for supermarkets, for example, are low, usually in the single digits in percent,[11] while margins for high-tech producers like Apple can reach the forties in percent.[12]

The low profit margins in food give patents a much stronger incentive effect in the food industry than in any other. The whole idea of patents is to incentivize investment in innovation by giving innovators and their backers a temporary (e.g. 20 year) legal monopoly in the results of innovation.[13]

Now imagine the effect of such an incentive on a food producer.

9. *See* Courtney Reagan, *What's Behind the Rush Into the Low-Margin Grocery Business*, CNBC (June 6, 2013, 10:59 AM), http://www.cnbc.com/id/100794988.

10. In classical economic theory, as distinguished from accounting, a "normal" profit is presumed included in the "cost" of goods. *See Costs of Production—Fixed and Variable Costs*, ECON. ONLINE, http://www.economicsonline.co.uk/Business_economics/Costs.html (last visited Jan. 14, 2015). Thus, when competition drives revenue down to marginal cost, that cost is presumed to include enough profit to keep the business running.

11. *See* THE REINVESTMENT FUND, UNDERSTANDING THE GROCERY INDUSTRY 9 chart 8 (2011), *available at* http://www.cdfifund.gov/what_we_do/resources/Understanding%20Grocery%20Industry_for%20fund_102411.pdf (reporting earnings, in the EBITDA margin, before interest, taxes, depreciation, and amortization for five supermarket chains as varying between -3% and +9.5% from 2006 through 2010); *see also* Aurelio Locsin, *The Average Profit Margin for a Restaurant*, CHRON, http://smallbusiness.chron.com/average-profit-margin-restaurant-13477.html (last visited Jan. 14, 2015) (reporting profits of full-service restaurants as ranging from 1.8% to 3.5%, depending on average menu prices).

12. *See* MORNINGSTAR, APPLE INC. ANALYST REPORT: VALUATION APR. 12, 2013 (predicting gross margin peaking at forty-four percent in fiscal year 2012, falling to thirty-eight percent in fiscal year 2013, and ultimately flattening out at the mid-thirties in percent long term) (on file with author).

13. 35 U.S.C. § 154(a)(2) (2012) ("Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . . .").

You are struggling along in a highly competitive industry, making profits in the low single digits. By developing something new that you can patent, you can, all of a sudden, enjoy a legal monopoly and exclusive rights. Your profit can soar overnight to the mid double-digits or higher, as long as your patent lasts. The lower the "background" level of profit without patents, as in the food business, the stronger the incentive to seek higher margins with patents.

B. Evolution

The second reason why food is different is evolution. Virtually everything we eat, and much of what we drink (other than pure water), comes from plants or other animals, with which we humans co-evolved. No one knows precisely how long that co-evolution took, but the best conservative guess is at least several hundred thousand years,[14] or an order of magnitude or two more than our species' entire recorded history.

During that long time, there were many false starts called "mutations."[15] There were also many instances of humans, driven by hunger, eating things they should not have. We do not see these mutations or unfortunate people anymore because they died out, in accordance with Darwin's law of natural selection.[16] The long, long process of biological co-evolution weeded out dangerous mutations and bad diets (whether forced or inadvertent) and left us with a range of known things we could eat without noxious side effects.

The much shorter process of human *social* evolution (a.k.a. civilization, including agriculture) taught us to cultivate and breed things that are nutritious and taste good. It also taught us not to eat poisonous things, including those with delayed or cumulative effects. In some cases, social evolution handed down ways of eating otherwise toxic things safely. An example is the poisonous and hallucinogenic mushrooms that mushroom-loving Russians eat, but only after boiling them for several hours to detoxify them.[17]

Now many food producers, driven by the profit motive and the

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14. According to a relatively authoritative summary, "Mammals didn't evolve until [200,000,000 years ago], and our own species, Homo sapiens, only 200,000 years ago." *See History of Life on Earth*, BBC, http://www.bbc.co.uk/nature/history_of_the_earth (last visited Jan. 7, 2015). Sometime between these two limits, the basic biology of us and our primate ancestors—including what we could and could not eat safely—was fixed.

15. *Natural Selection and Mutation,* NAT. CTR. FOR SCI. EDUC., http://ncse.com/book/export/html/1902 (last visited Jan., 10, 2015).

16. *Id.*

17. For an entertaining description of some of these mushrooms and the cultures that eat them, see Hank Shaw, *Eating Santa's Shroom*, HUNTER, ANGLER, GARDENER, COOK (Dec. 24, 2011), http://honest-food.net/2011/12/24/eating-santas-shroom/.

incentive of patents, want to duplicate those epochal processes of biological and social evolution on a much shorter time scale. They want to make innovations in food and have people eat them after a short period of testing (if any) by the Food and Drug Administration (FDA), generally on the time scale of a year or two. In sum, they want to short-circuit the co-evolutionary process by a factor of more than ten thousand. Some might call that hubris.

C. Complexity

The third reason why food is different, and the second scientific factor, is complexity. Our own human bodies (and minds) are the most complex things known to mankind.[18] These organic instruments are infinitely more complex than the most intricate *industrial* things we have built so far, for example, nuclear power plants and long-distance aircraft.

A Boeing 777 Worldliner, for example, has three million parts.[19] But the human *genome* alone has three *billion* base pairs.[20] Every DNA molecule in your body has the same number.[21] And those three billion base pairs interact in ways still largely unknown, to create a much larger complement of proteins and body fluids, in permutations and combinations that can become astronomical.

No wonder that, with all our computers and electronic and chemical technology, we are just beginning to understand how our bodies work, let alone our minds! And no wonder that, with all our nascent understanding of how probiotics work to aid digestion, sometimes our only sure cure for disease is the rather disgusting process of transferring feces from one person's gut to another's.[22]

When one does not understand things very well, it is hard to predict the outcome of changing them. For centuries, we have understood gravity well enough to predict the paths of artillery shells and ballistic missiles with a fair degree of accuracy. But the astronomically greater

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18. Alun Anderson, *Brain Work*, ECONOMIST (Nov. 17, 2011), http://www.economist.com/node/21537050 (noting that "[h]uman brains are the most complex objects in the known universe. Inside each one are some 100 billion nerve cells wired together with a million billion connections.").

19. *See 777 Family: Boeing 777 Facts*, BOEING, http://www.boeing.com/boeing/commercial/777family/pf/pf_facts.page? (last visited Jan. 7, 2015).

20. *The Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUMAN GENOME RES. INST., http://www.genome.gov/11006943 (last visited Jan. 10, 2015).

21. *Id.*

22. *See Quick, Inexpensive and a 90 Percent Cure Rate*, MAYO CLINIC, http://www.mayoclinic.org/medical-professionals/clinical-updates/digestive-diseases/quick-inexpensive-90-percent-cure-rate?_ga=1.231032668.2124202012.1413645309 (last visited Jan. 7, 2015) (discussing fecal transplant as cure for *Clostridium difficile* infection).

complexity of our own bodies and the biological world in which we live makes predicting the consequences of changes in food a hit-or-miss proposition.[23] The next section of this paper provides a few examples.

D. Agronomy

The final reason why food is different is an agronomical one. We humans—especially we Yanks—are something of faddists. When we invent something new that we like, we jump on the bandwagon with both feet. So it was with the insecticide DDT, as outlined below, and so it is with the iPad.

But imagine doing that with a staple crop like rice or wheat. Suppose we develop a new variety with greater yield or more resistance to pests. And suppose the world takes to it as to the iPad, making human civilization, or large parts of it, dependent on a single monoculture for food.

No innovation of ours can stop biological evolution, at least not yet. Pests and disease continue to evolve, just like the "superbugs" that are even now defeating our antibiotics. Now suppose a new pest develops—some blight or plant disease—that feeds on our new monoculture and kills it off. Poof, there goes the world's food supply.

Serious agronomists take this risk seriously. That is why, among many other things, there is a resurgence of interest in "heritage" strains[24] of everything from tomatoes to turkeys. The old strains may not offer the same profit as the new ones, but they may have better—or at least different—survival characteristics that help them withstand the ceaseless sifting of natural selection. In this context, genetic diversity is the key to long-term survival.

III. SOME EXAMPLES OF UNINTENDED CONSEQUENCES

The foregoing analysis of the unintended consequences of innovation relating to food is not just theory. Human history offers spectacular examples of difficulties, and even catastrophes, wrought by innovations that, at first glance, seemed beneficial.

23. For the effect of this fact on the difficulty of practical licensing of early-stage patents, see Jay Dratler, Jr., *Combinatorial Mathematics and the Problem of Early-Stage Patents in Biotechnology* (Univ. of Akron Legal Studies Research Paper No. 07-02, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=959462.

24. *Crop Plants and Their Relatives*, FOOD & AGRIC. ORG. UNITED NATIONS, http://www.fao.org/docrep/004/v1430e/V1430E04.htm (last visited Jan. 10, 2015).

A. The Irish Potato Famine

Perhaps the most poignant example is the Irish Potato Famine.[25] The humble potato was well adapted to Ireland's cool, damp climate, and it yielded more edible matter than other crops on the small farms that British rulers would let Irish Catholics own or rent. So the Irish came to plant more and more of it and to rely on it more heavily for their food supply. Along came the Irish potato blight of 1845, inadvertently imported from Mexico, and with it the Great Famine.

No cloud is without a silver lining. The Famine drove large numbers of Irish people to our Yankee shores,[26] including the ancestors of Presidents Kennedy and Reagan. Ireland's loss became our gain, but not without tremendous suffering, starvation, and social dislocation on that lovely green isle.

One might object that Ireland's potatoes were not patented. True enough. But today they might be. Even today, one can easily imagine an Irish Monsanto[27] developing a new potato by hybridizing or genetic engineering, and then marketing it heavily to most of Ireland's farmers. Along comes a new and improved blight, and you have a second Famine, assisted by all the splendor of modern technology and marketing.

B. The Story of DDT

The story of dichloro-diphenyl-trichloroethane is more apropos to our topic. DDT, as it is commonly known, is a powerful insecticide.[28] It *was* patented, first in Switzerland, then in Australia and the United States.[29] Its use exploded in the aftermath of World War II,[30] as Europe and Asia recovered from the War and the global economy took off. By controlling crop pests, DDT promised a whole new level of crop yields and productivity, especially in warmer climates with more pests.

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25. For a good, brief online history of this famine and its biological and social causes, see *The Irish Potato Famine*, DIGITAL HISTORY, http://www.digitalhistory.uh.edu/voices/irish_potato_famine.cfm (last visited Jan. 7, 2015).

26. *Id*.

27. "Monsanto is a sustainable agriculture company"; it delivers "agricultural products that support farmers around the world." *Monsanto at a Glance*, MONSANTO, http://www.monsanto.com/whoweare/pages/default.aspx (last visited Jan. 7, 2015).

28. For a succinct summary of the rise and fall of DDT to control crop pests and disease vectors, see *DDT - A Brief History and Status*, EPA, http://www2.epa.gov/ingredients-used-pesticide-products/ddt-brief-history-and-status (last visited Jan. 7, 2015) [hereinafter DDT].

29. *See Paul Müller – Biographical*, NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/medicine/laureates/1948/muller-bio.html (last visited Jan. 7, 2015) (providing a brief biography of DDT's inventor). For a 1952 U.S. patent on a combination of DDT with other insecticides, see U.S. Patent No. 2,600,668 (filed June 12, 1947) (issued June 15, 1952).

30. *See* DDT, *supra* note 28.

Then came the side effects.[31] Like many poisons, DDT was indiscriminate. Additional research later demonstrated that, like many poisons, it accumulated in fatty tissue.[32] It poisoned birds, too, making their eggshells thinner and their chicks much less likely to survive.[33] Then it started to affect the population of bees and wasps[34]—*good* insects on which human agriculture depends.

It took decades for these side effects to be noticed and their seriousness to be assessed. Today, DDT is banned in the United States and most developed nations, although its use persists in some third-world countries.[35]

No one knows for sure yet, but DDT and other insecticides may be responsible, in part, for today's "colony collapse" phenomenon, in which whole colonies of bees used for pollinating crops die off suddenly and inexplicably. Scientists' best guess today is that the cause of this agricultural disaster is a complex interaction among human pesticides, microbes and mites (microscopic bee parasites).[36] If so, this tragedy shows how the combination of incautious human innovation can interact with biological evolution in exceedingly complex ways to produce unintended consequences.

C. The Story of Bisphenol A

This story begins with the discovery of titanium and other catalysts for cheap polymerization by Karl Ziegler and Giulio Natta in the 1950s.[37] These catalysts, which work at room temperature and atmospheric pressure, made economic the production of a wide range of plastics, including polyethylene, polystyrene, and polypropylene.

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31. As is often the case, knowledge of DDT's side effects spread much more slowly than reports of its benefits. In his Nobel Prize lecture for discovering DDT in 1948, Müller reported, "Little or no mammalian or plant toxicity." Paul H. Müller, Dichloro-diphenyl-trichloroethane and Newer Insecticides, Nobel Lecture (Dec. 11, 1948) (transcript available at NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/medicine/laureates/1948/muller-lecture.pdf).

32. *See* DDT, *supra* note 28.

33. *Eggshell Thinning*, CRUISING CHEMISTRY, http://people.chem.duke.edu/~jds/cruise_chem/pest/eggs.html (last visited Jan. 10, 2015).

34. *Do Neonicotinoids Affect Other Wildlife as Well as Bees? The New DDT?*, NURTURING NATURE, http://nurturing-nature.co.uk/bumblebees-and-their-ecology/do-neonicotinoids-affect-other-wildlife-as-well-as-bees-the-new-ddt/ (last visited Jan. 10, 2015).

35. *See* DDT, *supra* note 28.

36. *The USDA's Top Bee Scientist Talks Pesticides and Colony Collapse at a D.C. Luncheon*, GRIST, http://grist.org/industrial-agriculture/2011-04-21-usda-bee-scientist-pesticide-research-pettis/ (last visited Jan. 10, 2015).

37. For a brief summary of the history of these discoveries, see *Petrochemistry and Synthetic Polymers*, CHEM. HERITAGE FOUND., http://www.chemheritage.org/discover/online-resources/chemistry-in-history/themes/petrochemistry-and-synthetic-polymers/index.aspx (last visited Jan. 7, 2015).

But various polymers have different properties of hardness, transparency, durability, and ductility. Some polymers are hard to work with and quick to degrade. In order to make them useful for industry and things like food packaging, they require plasticizers—i.e., chemicals used in their production and processing into finished products.

Enter Bisphenol A (BPA).[38] This chemical is a plasticizer used in polycarbonate plastic and the resin lining of many food and beverage cans.[39] Unfortunately, its chemical structure closely mimics that of estrogen, the human female hormone.[40] As a result, its leaching into food and drink stored in resin-lined containers causes such things as pre-cancerous changes in mammary and prostate glands, behavioral abnormalities and delayed onset of puberty in kids, reproductive abnormalities, and obesity and insulin resistance—precursors to diabetes.[41]

The mere listing of these conditions shows just how complex we human organisms are and how insidious may be the unintended consequences of ingesting even trace amounts of the wrong chemicals.

Hormones are among the most powerful natural chemicals in our bodies. And science is just now discovering that the "male" hormone testosterone and the "female" hormone estrogen have natural functions in each "opposite" gender and can, when in imbalance, produce various side effects and maladies in both genders.[42] So it is troubling, but should not be surprising, that an artificial chemical plasticizer that mimics estrogen in the body can have such diverse and deleterious effects.

The story of Bisphenol A is also instructive in another respect. The chemical was never intended to be or become a part of food or drink. Its purpose is to make containers better and easier to manufacture and use.[43] But when put in contact with food or drink in cans, bottles and other containers, it leaches into the food or drink, in tiny amounts, causing the unintended consequences summarized above.[44]

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38. For an outline of the uses of Bisphenol A, or BPA, and its known and suspected health impacts, see *Bisphenol A*, NRDC (Dec. 28, 2011), http://www.nrdc.org/living/chemicalindex/bisphenol-a.asp [hereinafter *Bisphenol A*].

39. *Id*.

40. *Id*.

41. *See generally* Anne Katchy et al., *Coexposure to Phytoestrogens and Bisphenol A Mimics Estrogenic Effects in an Additive Manner*, 138 TOXICOLOGICAL SCI., 2014, at 21-35; Cynthia Washam, *Exploring the Roots of Diabetes: Bisphenol A May Promote Insulin Resistance*, 114 ENVTL. HEALTH PERSP., Jan. 2006, at A48-49.

42. *See* Hector F. Escobar-Morreale et al., *The Striking Similarities in the Metabolic Associations of Female Androgen Excess and Male Androgen Deficiency*, 29 HUM. REPROD., no. 10, 2014, at 2083-91.

43. *See Bisphenol A*, *supra* note 38.

44. *See supra* text accompanying notes 39-41.

That is why my definition of "food patent" above is so broad. I wanted it to cover things like patents on Bisphenol A, which are part of the production, packaging and storage processes for food and drink, although not of the food or drink itself.

Pop-top cans do not appear in nature. As everyone who uses them knows (including me), they are a great convenience. They can keep drinks clean, easily available, and uncontaminated. They are easy to heat and cool. And you can dispose of them easily, even having some macho fun by crushing them in your hand. But in order to understand what they might be doing to your body, and especially to your kids, you have to dig deeper than their superficial characteristics, which are so easy to market.

D. Genetically Modified Organisms (GMOs)

The story of genetically modified organisms is just beginning. In the vanguard is Monsanto's "Roundup-Ready" soybean seed.[45] It appears to be coming to dominate the market (at least in the United States) in seeds for soybeans, which are one of humanity's most important staple crops, especially in Asia.[46] The United States Supreme Court recently strengthened the economic power of Monsanto's patent monopoly by forbidding farmers to grow soybeans from leftover or propagated patented seed without authorization.[47]

One consequence of this decision is the necessity of tracing the genetic origin of seeds. The decision requires farmers to put more effort into tracing for purposes of compensating Monsanto than it does for keeping track of crops' genetic origin for purposes of public health, safety, and consumer disclosure. Some might say that is a misallocation of priorities. But let us leave aside, for a moment, the troubling practical consequences of this decision.

There are other, much more fundamental, questions that Monsanto's seed patents raise. The seed is artificial in two respects. First,

45. For Monsanto's own marketing description of the advantages of these seeds, and how Monsanto intends to continue to control them with follow-on patents after the main patent expires, see *Roundup Ready Soybean Patent Expiration*, MONSANTO, http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx (last visited Jan. 7, 2015).

46. *See Soybean Seeds*, MONSANTO, http://www.monsanto.com/products/pages/soybean-seeds.aspx (last visited Jan. 7, 2015); *see also* Lance Gibson & Garren Benson, *Origin, History, and Uses of Soybean (Glycine Max)*, IOWA ST. UNIV., DEPT. OF AGRONOMY (2005), http://agron-www.agron.iastate.edu/Courses/agron212/Readings/Soy_history.htm (hyperlinked on Monsanto's website).

47. *See* Bowman v. Monsanto Co., 133 S. Ct 1761, 1764 (2013). The farmer, Bowman, bought seed intended for commodity use, not growing, from a grain elevator, knowing that a significant portion would have Monsanto's Roundup Ready genetic traits. The Court found this patent infringement and ruled the exhaustion doctrine inapplicable. *See id.* at 1765, 1769.

"Roundup," Monsanto's once-patented weed killer, uses a chemical product, glyphosate, that exploits detailed knowledge of weed physiology to selectively kill only certain types of weeds.[48] Second, Monsanto's patented soybean seed has been genetically modified to reduce the impact of Roundup on the patented soybeans and their yield.[49]

The result is a soybean whose Roundup-resistance is a genetic trait, which propagates automatically to future generations of soybean crops through seeds. This property also requires a peculiarity of patent protection, which now propagates to those very seeds, in order to preserve the economic incentive. Farmers can sell the seeds and eat them, but they cannot legally use them in farmers' normal way, by planting them to produce the next generation of crops.

So far, no unintended consequences have emerged except the surprise to farmers who can no longer do, with *these* seeds, what they have been doing with other seeds for millennia. But will the whole world, or large parts of Asia, rely on these seeds, like the Irish their potatoes, to their detriment in accommodating pests' evolutionary change? Will these genetic modifications, relating to weeds, herbicides, and soybean plants' resistance thereto, have unintended consequences in taste, health, durability of the soybean plants, or their resistance to constantly evolving natural pests other than competing weeds? And if this happens, how will we save our *other* crops from invasion and natural transfer of these new genes, when the only effort we have made to keep track of them is to insure Monsanto's patent profit?

We simply do not have answers to these questions. These new, genetically modified soybean plants are just a few years old. We humans have cultivated our crop plants, including soybeans, for millennia, and they took hundreds of millions of years to co-evolve with us.

In light of these simple facts, it would seem that triumphalism about food patents' ability to solve the "Malthusian" problem, let alone their freedom from unintended consequences, is premature. Irish potatoes, DDT, and Bisphenol A were not free from problems, and they were (or modified) much simpler systems than the complex genetics of plants and weeds. When we get to our *own* genetics—perhaps the most complex on our whole planet—we will encounter another order of complexity yet, with much greater risks of unintended consequences.

These four examples are far from the only cases of significant

48. *See* JOSEPH C. NEAL, POSTEMERGENCE, NON-SELECTIVE HERBICIDES FOR LANDSCAPES AND NURSERIES (1998), *available at* N.C. COOP. EXTENSION SERV., http://www.ces.ncsu.edu/hil/hil-648.html (last visited Jan. 7, 2015).

49. *Roundup Ready Soybeans*, PBS, http://www.pbs.org/wnet/dna/pop_genetic_gallery/page4.html (last visited Jan. 7, 2015).

unintended consequences from food-related innovations. I could also discuss the prions (unusually folded proteins) that introduced mad-cow disease into humans after we started feeding livestock with parts of other livestock's bodies containing nerve tissue, instead of the plant-based feed with which they evolved.[50] I could note the hole in our ozone layer caused by fluorocarbon refrigerants that, although not a biotech invention, certainly affected our biosphere.[51] (Patents on these refrigerants *do* fit within my broad definition of "food patents," as they are parts of systems for storing food.) I could also discuss what is perhaps the greatest unintended consequence of all—the global warming from our use of fossil fuels, which affects all living species, including our own.[52]

But this is a short concept paper, and by now you should have the general idea. *Any* innovation can have unintended consequences. But those that affect our infinitely complex brains and bodies (or our even more complex evolutionary biosphere) are likely to have the most subtle, insidious, and dangerous unintended consequences of all. Those that affect our food are foremost in this risky category.

IV. CONCLUSION

I am far from a Luddite. I have been a scientist and engineer myself, and I have spent decades proselytizing to developing markets in Asia on the benefits of IP protection. Free markets, strong competition, and the patents that promote innovation in them are indeed powerful and normally beneficial economic medicine.

But food is special. It is what we eat and therefore what we are. It is our principal means of short-term survival. And as we learn more about the astronomical complexity of our own bodies and brains, we ought to be more cautious about making quick changes, for short-term gain, in what nourishes and sustains them. Humility and caution, not triumphalism, are appropriate here.

Patents, of course, are not a regulatory mechanism. Their purpose is narrow: to promote and incentivize innovation and investment in it.[53] *Other* laws regulate and control things whose development patents might

50. *See generally* E. Norrby, *Prions and Protein-folding Diseases*, 270 J. INTERNAL MED., 2011, at 1-14.

51. *See* Elmar Uherek, *Chloroflurocarbons (CFC's) and the Ozone Hole*, ENVTL. SCI. PUBLISHED FOR EVERYBODY ROUND THE EARTH, http://www.atmosphere.mpg.de/enid/1z2.html (last visited Jan. 15, 2015).

52. *See, e.g.*, Indur M. Goklany, *Unintended Consequences*, N.Y. TIMES (Apr. 23, 2007), http://www.nytimes.com/2007/04/23/opinion/23iht-edgolany.1.5404935.html?_r=0.

53. U.S. CONST. art. I, § 8, cl. 8.

encourage, but that might be harmful.

This legal division of labor is clearest for drugs and medical devices. The U.S. Patent and Trademark Office decides whether an innovation is new, useful and nonobvious enough to warrant a patent, and the FDA determines whether it is safe and effective enough to be marketed. Of course there is some overlap, especially as concerns utility and effectiveness. A drug patent can issue if a biological invention works in the laboratory, while the FDA requires large field trials with actual patients before the drug can be marketed.[54]

But unaddressed practical problems remain. As the examples in this paper show, making food safe requires more precaution than just checking its named ingredients against a toxic substances list.

Some part of our government must create and maintain formal structures to avoid unintended consequences of food patents. Industry will not do it because that is not industry's function. Its function is to compete, sell, and make money, in part by innovating. The exclusive rights of patents give industry a powerful incentive to innovate in the low-margin, highly-competitive market for food. But patents give the food industry no incentive to second-guess the results of its own expensive innovation, let alone when regulatory burdens appear to block the long road to marketing approval just as that innovation is about to achieve payback.

The best model, in my view, is the FDA's regulation of drugs. Before loosing a new drug on the public and largely uncomprehending patients, the FDA requires rigorous scientific testing and proof of both effectiveness *and safety*.[55] And since nothing is ever 100% benign, it also requires rigorous collection and maintenance of post-marketing data on side effects, plus clear and prompt disclosure to doctors and their patients.[56] These data, which the FDA requires doctors and other health

54. The effect of this dual regime on actual marketing, commercial competition, and consequent remuneration has spawned one of the most complex interrelationships between federal statutes, of which the so-called Hatch-Waxman Act is the linchpin. Just explaining how the interrelationship is supposed to work requires longer text, as found in my treatise, than this short paper. *See* 1 JAY DRATLER, JR. & STEPHEN M. MCJOHN, LICENSING OF INTELLECTUAL PROPERTY § 5.02[2][a][iv][A] (1994) (discussing the Hatch-Waxman Act and its effect on marketing rights, patent duration, and commercial exclusivity).

55. 21 U.S.C. § 355(b)(1) (2012) (effective Mar. 13, 2013).

56. *See id.* § 355(r) (post-marketing surveillance for drugs); 21 U.S.C. § 360*l*(a)(l)(A) (2012) (post-marketing surveillance for medical devices). For the FDA's own summaries of these laws, see *Postmarket Drug and Biologic Safety Evaluations*, FDA, http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm204091.htm (last updated Jan. 2, 2015); *522 Postmarket Surveillance Studies – Frequently Asked Questions*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostmarketSurveillance/ucm134497.htm (last updated Nov. 3, 2014).

care providers to collect and disclose, are our early warning system for unintended consequences.

So far, the corresponding regulatory system for innovations covered by food patents is nascent at best, non-existent at worst. New foods, including modified genomes of existing plants and animals, do not qualify as "drugs." Therefore, they fall under the much more relaxed regulatory framework for food, with much less rigorous requirements for pre-marketing testing and post-marketing follow-up.

Worse yet is regulation of possible unintended genetic transfer in the world outside the laboratory. We know that microbes exchange genes; that is one way (besides spontaneous mutation) that they develop or acquire antibiotic resistance.[57] We also know that seeds and pollen blow and drift. Evolutionary studies suggest that seeds have blown and drifted as far as between continents, and that their having done so is responsible for the same or similar species appearing in widely different regions of Earth.[58]

If seeds can blow or drift between continents, surely they can get from one field to another, even in a neighboring country. Yet, science and the EPA are just beginning to address the possibility of Monsanto's "Round-up Ready" soybean seeds taking root where no one intended them to be.[59] The problem is not just compensating Monsanto; it is physical and genetic contamination, which might become irreversible.

There is a lot about our biosphere that we still do not know. Just a few decades ago, we did not know that unusually-folded proteins called "prions" could cause a human variant of mad-cow disease, resulting in a horrible, slow death for victims.[60] We also did not know that the causative agent could be passed from animal to animal through alimentation.[61] Now we know, and our food chain is safer.

Yet what we still do *not* know about other things could hurt us.

57. University of Gothenburg, *Antibiotic Resistance Spreads Rapidly Between Bacteria,* SCIENCEDAILY (Apr. 13, 2011), http://www.sciencedaily.com/releases/2011/04/110411163918.htm.

58. Matin Miryeganeh et al., *Long-Distance Dispersal by Sea-Drifted Seeds Has Maintained the Global Distribution of Ipomoea pes-caprae subsp. brasiliensis (Convolvulaceae)*, PLOS ONE, http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0091836 (last visited Jan. 10, 2015).

59. Today the extent to which the natural drift of seeds and pollen causes new genes to migrate among open fields is largely unknown and politically controversial. For a recent review of the science, see Natasha Gilbert, *Case Studies: A Hard Look at GM Crops*, NATURE (May 1, 2013), http://www.nature.com/news/case-studies-a-hard-look-at-gm-crops-1.12907. For citations to the scientific literature and anecdotal evidence of drift, see *id*.; *see also* Benjamin M. Cole, Brent J. Horton, & Ryan Vacca, *Food for Thought: Genetically Modified Seeds as de Facto Standard-Essential Patents*, 85 U. COLO. L. REV. 313, 324-26 & nn.74 & 77 (2014).

60. *See generally* Norrby, *supra* note 50.

61. *Id*.

And it could hurt us badly if the unintended consequence comes from an innovation that seems especially promising but which has unfortunate side effects that take a long time to notice and an even longer time to prove.

So we have a lot of work to do in ensuring that the innovations in food, which our food patents so strongly encourage, are safe. That work is just beginning. It is not as intrinsically "exciting" or newsworthy as the innovation itself. But it is vitally necessary for our collective health, welfare and, perhaps, even our survival. Remember the Irish Potato Famine.

Innovative triumphalists love to point out that our species has been mixing genes in plant and animal hybridization for hundreds of years. That is true. But we have been mixing naturally occurring genes, not artificial ones. We have now reached the point where we can "invent" genes that never occurred in nature, or transfer ones between species that never could have exchanged genes through natural reproduction or any known means of hybridization.

We are messing with the Earth's biosphere and with our own molecular biology, as we never before could. That does not mean we should stop. Technological progress is one of our own species' chief evolutionary advantages. It just means that we should be more careful and more vigilant for unintended consequences, especially as our innovations get more subtle and complex.

Proper regulation does not necessarily mean banning useful innovations. Again, the FDA provides a good model, restricting powerful drugs to uses for which they are safe, or uses in which the probable benefits to otherwise suffering or dying patients outweigh the risks, and banning the rest. If we had been more careful with DDT, we might have found uses for it in which sun and weather degrade it before it enters the biosphere or the food chain. And we might have done so before we allowed it to pollute much of our agricultural biosphere and our own body fats.

But insofar as it concerns innovations relating to food, we have been careless to the point of negligence. We need a comprehensive and thorough regulatory counterweight to food patents, analogous to the FDA regulations for new drugs.

Innovators like Monsanto, Karl Ziegler, and Steve Jobs are the very public heroes of our modern society. But our regulators are also heroes, albeit largely unsung. They also serve, who only watch for bugs.