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FOOD AND DRUG LAW AS INTELLECTUAL PROPERTY LAW: HISTORICAL REFLECTIONS

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FOOD AND DRUG LAW AS INTELLECTUAL PROPERTY LAW: HISTORICAL REFLECTIONS

KARA W. SWANSON*

This Article returns to the turn of the twentieth century to consider food and drug law as intellectual property law. Today, Americans are engaged in two separate debates about food and drugs, one centering on safety and the effectiveness of the Food and Drug Administration, and the other on patent law and questions of equity, pricing, and profits. Arguing both that early food and drug law was influenced by intellectual property concerns and that the separation of intellectual property policy from federal food and drug regulation was neither inevitable nor inconsequential, this Article uses an historical perspective to understand the separation of these debates and to consider the opportunities that arise from considering food and drug law as intellectual property law.

Drawing on the history of science, technology, and medicine, this Article reexamines the early pure-food-and-drug movement as, in part, an anti-intellectual-property movement, concentrating on the problems of trade secrets in food and drug markets. It reviews the alliance between medical opponents to proprietary medicines and agricultural opponents to artificial foods that successfully supported early federal food and drug regulation, and the simultaneous failure of a medical campaign against drug patents. By considering the early twentieth-century shift in the drug market from reliance on trade secrets to reliance on patents in relationship to the recent move toward patents in agribusiness, this Article considers the lessons from history for a reunification of food and drug policy with intellectual property policy.

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INTRODUCTION

At the turn of the twenty-first century, Americans are inundated with news stories suggesting that their food and drugs are not safe. Manufacturers have recalled foods from grocery shelves and restaurant kitchens after outbreaks of food poisoning and have withdrawn approved drugs from the market after some patients experienced serious side effects. Both eating food and taking prescription medicine can lead to death. These news stories focus attention on the obligation of the U.S. Food and Drug Administration (FDA) to inspect processing plants and factories and review data from clinical trials of drugs.[1] Often, critics suggest that the FDA is inadequately funded to perform this inspection role well and that it is too quick to approve drugs.[2] Other critics identify overregulation by the same agency and unwarranted

1. *See, e.g.*, Gardiner Harris, *Food Products Recalled for Salmonella*, N.Y. TIMES, Mar. 5, 2010; Gardiner Harris, *President Plans Team to Overhaul Food Safety*, N.Y. TIMES, Mar. 15, 2009, at A24; *House Panel Criticizes F.D.A. Role in Drug Cases*, N.Y. TIMES, Apr. 23, 2008, at A7; Marc Kaufman, *Controversial Diabetes Drug Is Withdrawn*, WASH. POST, Mar. 22, 2000, at A1; Andrew Martin, *Filling Safety Gap, Growers Pay for Inspectors*, N.Y. TIMES, Apr. 17, 2009, at A1. These criticisms led to a new food safety bill in 2011, the FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

2. *See, e.g.*, Reed Abelson, *Quickly Vetted, Treatment Is Offered to Cancer Patients*, N.Y. TIMES, Oct. 27, 2008, at A1; Robert Cohen & Edward R. Silverman, *Drug Recalls Rise After Fast FDA Approval*, STAR-LEDGER (Newark), June 28, 1998, at 1; Editorial, *The F.D.A. in Crisis*, N.Y. TIMES, Feb. 3, 2008, at WK14; Gardiner Harris, *More Money for Food Safety Is Sought*, N.Y. TIMES, June 10, 2008, at A17; Gardiner Harris, *Study Condemns F.D.A.'s Handling of Drug Safety*, N.Y. TIMES, Sept. 23, 2006, at A1; *see also* HERBERT BURKHOLZ, THE FDA FOLLIES 1–4 (1994) (summarizing criticism of FDA during 1980s as "bumbling and inefficient").

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hesitancy to approve life-saving cures.[3] We expect the FDA to ensure the safety of our food and drugs so that we can depend on the products we buy.

These debates over the FDA and safety are largely distinct from discussions about the appropriate role of intellectual property in the food and drug markets. The increasing use of patents to protect genetically modified plants and animals has led to fierce criticism of the ownership of internationally significant crops,[4] while the prominence of patents in the pharmaceutical market has drawn critical attention since the 1950s.[5] Whether patents are an appropriate means of allowing companies to recoup significant costs in research and development of life-enhancing drugs or an unjust means to monopoly pricing that precludes the neediest from obtaining medication remains an unresolved and hotly debated question.[6] The agency examined in these discussions is the U.S. Patent and Trademark Office and its administration of the patent laws. Questions about equity, pricing, and profits are considered separately from safety.

Over one hundred years ago, before the FDA existed, Americans were inundated with similar news stories about food and drug safety. Muckraking journalists and sober medical journals alike told Americans how they were being treated like "guinea pigs" by taking unknown medicines and eating foods laced with potentially harmful preservatives.[7] Rather than being provided with pure food and drugs,

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3. Harris, *Study Condemns F.D.A.'s Handling of Drug Safety*, *supra* note 2; Gardiner Harris, *Where Progress Is Rare, the Man Who Says No*, N.Y. TIMES, Sept. 16, 2009, at A1; Andrew Pollack, *New Sense of Caution at F.D.A.*, N.Y. TIMES, Sept. 29, 2006, at C1.

4. *See* KEITH AOKI, SEED WARS: CONTROVERSIES AND CASES ON PLANT GENETIC RESOURCES AND INTELLECTUAL PROPERTY xiii-xv (2008) (explaining the origins of the term "seed wars" and the broad contours of the debate); VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 2–4 (1997); Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply—Past, Present, and Future*, 2011 WIS. L. REV. 397 [hereinafter Aoki, *Food Forethought*].

5. Senator Estes Kefauver held hearings in 1959 focused on drug pricing as a function of monopoly power. PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 122 (1980).

6. *See, e.g.*, RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION (2006); Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004); William W. Fisher III, The Intersection of Intergenerational and International Equity: Developing Drugs for Developing Countries, Paper Presented at the Wisconsin Law Review Symposium (Nov. 12–13, 2010).

7. The chief muckraking publications in this area at the turn of the century were *Collier's Weekly* and *Ladies Home Journal*. STEPHEN WILSON, FOOD AND DRUG REGULATION 22–27 (1942); C.C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3, 7 (1933). Articles from *Collier's* were

the next generation was being offered adulterated, mislabeled goods that, at best, were not worth the money paid for them, and, at worst, threatened malnutrition, addiction, and death. To many, the best solution seemed to be federal legislation. In 1906, the advocates for federal action succeeded when the Pure Food and Drugs Act ("1906 Act")[8] granted regulatory powers to what became the FDA.[9] After three decades of further agitation, Congress expanded the powers of the new agency by passing the Food, Drug, and Cosmetic Act of 1938 ("1938 Act").[10]

These first federal food and drug laws have often been explained as legislation exemplifying distinctive political moments. The 1906 Act has long been understood as a key example of Progressivism, creating the first federal consumer agency in the glow of faith in science and

reprinted in SAMUEL HOPKINS ADAMS, THE GREAT AMERICAN FRAUD (5th ed. 1912) (focusing on drugs). Consumers' Research, Inc., founded in 1929, supported the publication of ARTHUR KALLET & F.J. SCHLINK, 100,000,000 GUINEA PIGS: DANGERS IN EVERYDAY FOODS, DRUGS, AND COSMETICS (1933), which criticized food and drugs on the market as unsafe. The AMA published weekly articles on medicines in the *Journal of the American Medical Association*, which articles were re-published in an inexpensive pamphlet form for public distribution and eventually gathered into three volumes of books. Arthur J. Cramp, *The Work of the Bureau of Investigation*, 1 LAW & CONTEMP. PROBS. 51, 53 (1933); *see also* JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906, at 31–39, 110–12 (1989) (discussing history of food and drug concerns before 1906).

8. Pure Food and Drugs Act, ch. 384, 34 Stat. 768 (1906).

9. In 1906, enforcement powers were given to what was then called the Chemistry Bureau within the Department of Agriculture. The Food and Drug Administration was formally established as the Food, Drug and Insecticide Administration in 1927 and gained its present name in 1930. Act of Jan. 15, 1927, Pub. L. No. 69-551, 44 Stat. 976, 1002 (1927); Act of May 27, 1930, Pub. L. No. 71-272, 46 Stat. 392, 422–23 (1930). For early bureaucratic changes, see GUSTAVUS A. WEBER, THE FOOD, DRUG, AND INSECTICIDE ADMINISTRATION: ITS HISTORY, ACTIVITIES AND ORGANIZATION (1928), and Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FOOD DRUG COSM. L.J. 17, 18 (1990).

10. Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). For a contemporaneous description of the perceived inadequacies in the 1906 Act, necessitating further regulation, see RUTH DEFOREST LAMB, AMERICAN CHAMBER OF HORRORS: THE TRUTH ABOUT FOOD AND DRUGS (1936); 1 NOSTRUMS AND QUACKERY (1912) (reprinting articles published in the *Journal of the American Medical Association* from 1907 to 1911); 2 NOSTRUMS AND QUACKERY (Arthur J. Cramp ed., 1921) (reprinting articles published in the *Journal of the American Medical Association* from 1912 to 1921); ARTHUR J. CRAMP, 3 NOSTRUMS AND QUACKERY AND PSEUDO-MEDICINE (1936) (condensation of articles appearing in the *Journal of the American Medical Association*, *Hygeia*, *American Mercury*, and in the Bureau of Investigation's AMA pamphlets); *see also* Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 1 FOOD DRUG COSM. L.Q. 532, 533-36 (1946).

expertise to solve market failures and better the human condition.[11] The 1938 Act passed during the New Deal era when there was similar enthusiasm for expertise to better American life through federal oversight and intervention.[12] Historians and political scientists have considered the interest groups involved and have portrayed the bills both as products of newly emergent consumer activism[13] and as classic cases of industry-directed regulation that aided big business at the expense of small, local business.[14]

Remarkably, given the increasing focus in recent decades on the role of intellectual property in markets for food and drugs, there has been little focus on intellectual property within this history of early federal food and drug law.[15] By taking such a focus, this Article reveals that contemporary concern about intellectual property in food and drugs has historical antecedents that influenced the structure of modern food and drug law. An articulated concern with the use of intellectual property helped unite the interest groups that supported passage of the 1906 and 1938 Acts. At the turn of the twentieth century, it was trade secrets that were perceived as the chief evil in the food and drug markets, rather than patents. In the last decades of the nineteenth century, participants in the pure-food-and-drug movement broadened their campaign into a campaign against secrecy as well as against adulteration, linking improved public safety with better public

11. PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION, xi (2003); TEMIN, *supra* note 5, at 18; Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States*, 37 FOOD DRUG COSM. L.J. 310, 310 (1982); Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1225–28 (1986); Regier, *supra* note 7, at 3-15.

12. CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL vii (1970) (describing the 1938 Act as a "reaction" to the "significant and dramatic impact of science"); Laurence V. Burton, *What the Food Manufacturer Thinks of S. 1944*, 1 LAW & CONTEMP. PROBS. 120, 120 (1933) (describing a precursor to the 1938 Act as motivated by the same enthusiasm for expertise as other New Deal legislation).

13. *See, generally,* LORINE SWAINSTON GOODWIN, THE PURE FOOD, DRINK, AND DRUG CRUSADERS, 1879-1914 (1999).

14. CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY (1999); JACKSON, *supra* note 12, at 204–20 (describing relative influences of consumer groups and industry in the passage of the 1938 Act and reviewing earlier historiography); DONNA J. WOOD, STRATEGIC USES OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA (1986) (describing how 1906 Act resulted from strategic decisions by food and drug companies). The historiography of the 1906 Act is reviewed in YOUNG, *supra* note 7, at 273-91.

15. "Intellectual property" was not a term much used until the late twentieth century, but for convenience, I use it to refer to patents, copyrights, trademarks, and trade secrets during this earlier period.

knowledge. What today are often seen as separate issues—consumer safety and intellectual property policy—were combined under the banner of "pure food and drugs." As an anti-secrecy campaign, the pure-food-and-drug movement became, in part, a movement to adjust the way intellectual property was used in the food and drug markets. The result was anti-trade-secret legislation that significantly eliminated trade secrets as a legal option for food and drug producers, while doing little to directly regulate the content, safety, or efficacy of food and drugs.

Ironically, while many of the reformers did not intend to replace the previous trade-secret regime with a patent-based regime, the federal regulations aided such a shift. The destruction of trade secrets as an option for protecting commercial interests in food and drugs became part of the conditions of possibility supporting the reliance of drug manufacturers on patents.[16] At the same time, the medical profession dropped its long-standing opposition to medical patents, further assisting the emergence of patents as the dominant form of intellectual property in the drug market. The successful use of patents in the drug market by large pharmaceutical corporations in the second half of the twentieth century in turn became part of the conditions of possibility undergirding the more recent, and highly controversial, move toward patented foods and seeds.[17]

This Article reexamines the history of early federal food and drug regulation from the perspective of intellectual property, and with deliberate presentist consciousness of these later controversies. Through this reexamination, I seek to explain and highlight the opposition to trade secrets in the early pure-food-and-drug campaign, as well as the rapid repositioning of patents within the drug industry.[18] Beginning in Part I with a review of the traditional political, social, and economic historiography of these statutes, I layer onto these narratives the history of science and medicine in the second half of the nineteenth century.

16. I use the phrase "conditions of possibility" to describe historical relationships in a Foucauldian sense to avoid a suggestion of unilateral causality. *See, e.g.*, ARNOLD I. DAVIDSON, THE EMERGENCE OF SEXUALITY: HISTORICAL EPISTEMOLOGY AND THE FORMATION OF CONCEPTS 202–03 (2001) (describing Foucault's historical epistemology).

17. For the controversy about food and seed patents, see *infra* Part IV, and Aoki, *Food Forethought*, *supra* note 4.

18. As a reexamination of the history of early food and drug regulation, this Article relies upon existing secondary work in the history of food and drug regulation, science and medicine, along with legal sources such as patents, statutes, and cases. While the footnotes reflect the limited review I have made of the scientific, medical, and policy literatures of the examined time period, this Article is based primarily on using a novel perspective to reconsider existing historiography.

New ways of seeing and knowing through science reshaped both the epistemology and ontology of pure food and drugs in ways that redefined the age-old problem of purity, making federal anti-secrecy legislation a preferred solution. In Part II, I explore the turn-of-the-century pure-food-and-drug movement as a movement against trade secrets by explaining the use of trade secrets in the food and drug industries, the opposition to secrecy, and the resulting legislation. In Part III, I turn to patents, first outlining the opposition of the medical profession to medical patents, and then describing early experience with drug patents in the first decades of scientific medicine and the transformation of medical opinion during the 1930s. Finally, in Part IV, I consider the lessons from this reevaluation of history, exploring the split between food-and-drug-safety regulation and intellectual property after 1938 and suggesting that the current moment offers opportunities for a fruitful return to consideration of food and drug law as intellectual property law.

I. RECASTING THE HISTORY OF EARLY FOOD AND DRUG REGULATION

A. The Traditional Story of Legislative Reform

The simplest understanding of the early food and drug acts links passage of each law to an event causing national outrage, creating the legislative will to regulate the food and drug markets. The Pure Food and Drugs Act of 1906 passed within a year after the publication of Upton Sinclair's wildly successful novel, *The Jungle*, an exposé of the Chicago meat-packing industry.[19] Sinclair's description of the industry's callous indifference to the health of the consuming public was widely known to have been based on Sinclair's firsthand research. After publication of the novel, meat sales in the United States plummeted, and public fear and outrage helped push the Act through Congress.[20] Similarly, the Food, Drug, and Cosmetic Act of 1938 passed after a nationwide scandal about deaths caused by a liquid preparation of a new

19. UPTON SINCLAIR, THE JUNGLE (1906).

20. *See* James Harvey Young, *The Pig That Fell into the Privy: Upton Sinclair's* The Jungle *and the Meat Inspection Amendments of 1906*, 59 BULL. HIST. MED. 467 (1985); *see also* YOUNG, *supra* note 7, at 221–52. For confirmation of Sinclair's facts, see *id.* at 224; for drop in meat sales, see *id.* at 231. Ironically, Sinclair's object was to spark public outrage about the *labor* practices in the meat-packing industry and win advocates to socialism, rather than to spur food-safety legislation. *Id.* at 229. Also note that meat was not covered by the 1906 Act, but by the separate Meat Inspection Act (June 30, 1906), signed into law on the same day. *Id.* at 262.

drug, sulfanilamide.[21] The manufacturer had suspended the drug in a poison, diethylene glycol, causing the painful deaths of many who consumed it.[22] Because of the limitations of the 1906 Act, this tragedy occurred virtually without any lawbreaking.[23] Again, public outrage helped sweep a pending bill through Congress.[24]

While accurate, these stories of public outrage ignore the decades of agitation that preceded each final push to pass legislation. Detailed studies of the legislative history of the bills, and their ultimate provisions, provide a more nuanced context.[25] The acts each had roots in activism that preceded not only *The Jungle*, but also Progressivism itself. Adulteration is not a modern problem, having been a focus of governments since antiquity.[26] During the nineteenth century, however, there was a series of social changes that changed the nature of this long-standing problem, supporting a movement for federal regulation as a new way of addressing it. These changes were gradual, as was the turn to new legislative solutions.[27]

The traditional, historically rich narrative of the pure-food-and-drug movement includes three interrelated precipitating changes: urbanization, industrialization, and professionalization. These trends, which accelerated as the nineteenth century advanced, had broad effects across U.S. society, supporting the late-nineteenth-century emergence

21. JACKSON, *supra* note 12, at 152–74.

22. *Id.* at 153-56.

23. The manufacturer's only legal misstep under the 1906 Act was labeling the suspension an "elixir," a term defined as an alcohol suspension, which the product was not. Without that misstep, the sale of the deadly medication would have been completely legal under federal law. The manufacturer had no obligation to ensure the safety of the preparation. *Id.* at 156–57.

24. Although beyond the scope of this paper, the 1962 Kefauver-Harris amendments to the Federal Food, Drug, and Cosmetic Act, Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962), which tightened the process of introducing a new drug to the marketplace, are often explained similarly as a legislative reaction to the public outrage about birth defects caused by the drug thalidomide. TEMIN, *supra* note 5, at 123-26. In that case, Senator Estes Kefauver had been pushing for a revision since 1959, focusing not on the question of safety, but on pricing. *Id.* at 122.

25. JACKSON, *supra* note 12, at 49-65 (discussing the 1938 Act); YOUNG, *supra* note 7, at 253-72 (discussing the 1906 Act).

26. WILSON, *supra* note 7, at 7–8; F. Leslie Hart, *A History of the Adulteration of Food Before 1906*, 7 FOOD DRUG COSM. L.J. 5, 7–13 (1952).

27. For a thorough discussion of the nineteenth-century pure-food-and-drug movements, see MITCHELL OKUN, FAIR PLAY IN THE MARKETPLACE: THE FIRST BATTLE FOR PURE FOOD AND DRUGS (1986) (concentrating on 1865–1886), and GOODWIN, *supra* note 13 (concentrating on 1874–1914).

of a modern capitalist economy and its accompanying legal system.[28] The burgeoning cities required regional and national markets to support their population. The market for milk and other dairy products provides a clear example of the effects of urbanization. In place of very local markets, virtually the entire dairy output of Pennsylvania and New York became directed toward supplying milk to the cities of the Northeast.[29] These markets replaced local economies in which the feedback loop between buyers and sellers provided a natural check on consumer fraud. The related trend of industrialization exacerbated this shift. Large-scale processing in factories created new opportunities for adulteration, and further separated production and consumption. As the dairy market became industrialized, cheese and butter production shifted from individual farms to factories, and the dairy output of the less population-dense Midwest (particularly Wisconsin and Minnesota) became directed toward the production of these shelf-stable products.[30] Through urbanization, consumers and producers became strangers to each other, separated by distance, and through industrialization, dairy products also became strange to consumers, created by mechanisms of production that were no longer part of the general knowledge of an agrarian population.[31]

The social upheavals of urbanization and industrialization and the emergence of a modern, capitalist-industrial economy fed a middle-class struggle for status and income, manifested in part in the general push toward professionalization in many occupations.[32] This effort is particularly relevant to the history of food and drug regulation as it applies to chemists, doctors, and pharmacists. Each of these groups was attempting to carve out stable career paths during this period, seeking to build the traditional indicia of a profession: formal educational requirements, licensure, professional societies, and professional

28. *See generally* ALFRED D. CHANDLER, JR., THE VISIBLE HAND: THE MANAGERIAL REVOLUTION IN AMERICAN BUSINESS (1977); MORTON J. HORWITZ, THE TRANSFORMATION OF AMERICAN LAW, 1870–1960: THE CRISIS OF LEGAL ORTHODOXY (1992); ROBERT H. WIEBE, THE SEARCH FOR ORDER: 1877-1920 (1967).

29. W.R. PABST, JR., BUTTER AND OLEOMARGARINE: AN ANALYSIS OF COMPETING COMMODITIES 16 (1937).

30. *Id.* at 16. For further discussion of the industrialization of the dairy industry, see E. MELANIE DUPUIS, NATURE'S PERFECT FOOD: HOW MILK BECAME AMERICA'S DRINK 125–43 (2002).

31. These shifts and their consequences are not only discussed by historians, see WILLIAM CRONON, NATURE'S METROPOLIS: CHICAGO AND THE GREAT WEST 97–147, 207–59 (1991), but were apparent to pure-food-and-drug reformers at the time. *See, e.g.*, Regier, *supra* note 7, at 3 (explaining the need for law as due in part to the shift from an "agricultural society" to an "industrial society").

32. WIEBE, *supra* note 28, at 112–21; Nathan O. Hatch, *Introduction* to THE PROFESSIONS IN AMERICAN HISTORY 1, 6 (Nathan O. Hatch ed., 1988).

journals. Scientists barely existed in the United States in the early republic, and the United States only slowly began to offer paying jobs in science, first through the federal government and later through university professorships and industry jobs. Throughout the second half of the nineteenth century, scientifically trained men (and a few women) sought ways of putting their knowledge to work to support themselves and to better society.[33] By the end of the nineteenth century, chemistry was a rapidly growing area of science, and scientists were applying chemical knowledge and techniques to biological and medical problems.[34]

Medical doctors began the nineteenth century in a weak position, only one of a plethora of healing options available to Americans.[35] It would take over one hundred years for formally trained, allopathic physicians to consolidate the taken-for-granted status as the preferred medical professionals that they then maintained through the second half of the twentieth century.[36] In this process, doctors both competed with and attempted to ally with pharmacists, who were also jockeying for recognition.[37] While the efforts of medical doctors, chemists, and pharmacists to professionalize did not cause the pure-food-and-drug problem, these professional groups became interest groups involved in the movement for change, both because of their articulated concern for the public health, and as part of their struggles for status.

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33. *See generally* A. HUNTER DUPREE, SCIENCE IN THE FEDERAL GOVERNMENT: A HISTORY OF POLICIES AND ACTIVITIES TO 1940 (1957); SALLY KOHLSTEDT, THE FORMATION OF THE AMERICAN SCIENTIFIC COMMUNITY: THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, 1848-60 (1976); Daniel J. Kevles, *American Science*, *in* THE PROFESSIONS IN AMERICAN HISTORY, *supra* note 32, at 107, 110–13.

34. A CENTURY OF CHEMISTRY: THE ROLE OF CHEMISTS AND THE AMERICAN CHEMICAL SOCIETY 1–3 (Kenneth M. Reese & Herman Skolnik eds., 1976); ROBERT E. KOHLER, FROM MEDICAL CHEMISTRY TO BIOCHEMISTRY: THE MAKING OF A BIOMEDICAL DISCIPLINE 97–108 (1982).

35. JOSEPH F. KETT, THE FORMATION OF THE AMERICAN MEDICAL PROFESSION: THE ROLE OF INSTITUTIONS, 1780-1860, at vii, 3-4, 30–31 (1968).

36. WILLIAM G. ROTHSTEIN, AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY: FROM SECTS TO SCIENCE 326 (1972); PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 4, 7–8 (1982); Ronald L. Numbers, *The Fall and Rise of the American Medical Profession*, *in* THE PROFESSIONS IN AMERICAN HISTORY, *supra* note 32, at 51, 51–72.

37. JONATHAN LIEBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY: THE FORMATION OF THE AMERICAN PHARMACEUTICAL INDUSTRY 20–24, 26–29 (1987); Glenn Sonnedecker, *Contribution of the Pharmaceutical Profession Toward Controlling the Quality of Drugs in the Nineteenth Century*, *in* SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL 97, 97–111 (John B. Blake ed., 1970).

B. Adding Science and Medicine Perspectives

The history of early food and drug regulation cannot be fully understood as an intellectual property story without supplementing this traditional narrative with the history of medicine and science during the late nineteenth century. By considering this history, we can better understand how the pure-food-and-drugs problem came to be understood in ways redressable by federal legislation, and in particular, by regulation against secrecy. The history of medicine and science contributes to a more complete understanding of the linkage of food and drugs through the shared problem of adulteration, and the recasting of the age-old problem of adulteration into a problem of secrecy.

1. FOOD AND DRUGS IN THE MEDICAL MARKETPLACE

At a basic level, the purity of food and drugs were considered together intermittently throughout the nineteenth century simply because both were ingested. Something harmful in either type of product threatened the physical well-being of the consuming public, distinguishing fraud and poor quality in these markets from other types of commercial chicanery. But the relationship between the two was not limited to the shared risks of ingestion. Throughout much of the nineteenth century, the boundary between food and drugs was porous.[38] As the so-called heroic therapies of the early republic, such as purging and bloodletting, became less common,[39] doctors relied on the careful manipulation of diet to treat patients. Foods, as well as alcoholic beverages, were medicines, prescribed in precise quantities.[40]

In the unregulated free-for-all that was the medical marketplace during the nineteenth century, Americans could choose among a wide variety of medical theories and practitioners when seeking assistance. Allopathic physicians, working from Galenic notions of humors and balance, considered themselves to be the true medical professionals but often had very little formal training as medical schools went unregulated. Some physicians traveled to Europe to obtain a more rigorous medical education; others made do with a few months of

38. Lewis A. Grossman, *Food, Drugs, and Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law,* 93 CORNELL L. REV. 1091, 1106 (2008).

39. JOHN HARLEY WARNER, THE THERAPEUTIC PERSPECTIVE: MEDICAL PRACTICE, KNOWLEDGE AND IDENTITY IN AMERICA, 1820-1885, at 91–95 (1986).

40. LIEBENAU, *supra* note 37, at 13 (describing the prescription of diet and stimulants (which were usually alcohol)); WARNER, *supra* note 39, at 98–99; YOUNG, *supra* note 7, at 20–21, 23-24, 27, 30.

uninspired lectures at a for-profit school in the United States.[41] They faced competition from Thomsonians (practitioners of a botanically based system of treatment),[42] homeopaths, lay practitioners, midwives, and barbers. Different healers might emphasize food, waters, diet, or mineral drugs. In this atmosphere, even defining the term "drug" could be both problematic and controversial.[43] While the self-described "regular" or allopathic physicians tried to characterize other practitioners as "irregulars," Americans as a whole rejected that dichotomy and experimented with a range of medical care, including self-care, following a wide variety of theoretical approaches.[44]

Just as "regular" doctors competed with other types of practitioners for patients, pharmacists competed with other suppliers of medicines. While pharmacists maintained a stock of different mineral and botanical compounds from which to mix medicines, doctors might mix their prescriptions themselves, rather than sending a patient to a pharmacy with a prescription. Pharmacists also sold directly to consumers without a prescription. Individuals could buy from their local drug retailer raw ingredients, mixtures compounded by the pharmacists, or pre-mixed, packaged compounds, often called "proprietary medicines."[45] In direct-to-consumer sales of proprietary medicines, pharmacists faced competition from grocers and general stores that also sold such medicines.[46] Thus, the linkage of food and drugs, the very definition of "drug," and the drug market were tied into the chaotic marketplace for medical care, in which multiple groups jockeyed for patients, and Americans freely engaged in self-treatment, both by manipulating their diets and self-medicating with purchased drugs.

2. NEW WAYS OF SEEING AND KNOWING FOOD AND DRUGS

During the second half of the nineteenth century, there was a slow development of scientific knowledge that resulted in an even slower

41. KENNETH M. LUDMERER, LEARNING TO HEAL: THE DEVELOPMENT OF AMERICAN MEDICAL EDUCATION 11–15, 18, 32–33 (1985); ROTHSTEIN, *supra* note 36, at 89, 94.

42. *See* KETT, *supra* note 35, at 97–131; ROTHSTEIN, *supra* note 36, at 125–511 JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 44–57 (1961).

43. Grossman, *supra* note 38, at 1104–08, 1114–16 (describing the struggle to define "drug" in law).

44. KETT, *supra* note 35, at 1–5; ROTHSTEIN, *supra* note 36, at 125, 152; Numbers, *supra* note 36, at 58–61;

45. LIEBENAU, *supra* note 37, at 13-14.

46. YOUNG, *supra* note 42, at 9.

therapeutic transformation based on what would come to be known as "scientific medicine."[47] The therapeutic transformation resulted in the introduction of vaccines, chemotherapies, and antibiotics, man-made compounds that promised to cure diseases.[48] These new scientifically based therapeutics were just beginning to transform medical practice at the turn of the twentieth century and became available at a rapid rate after World War II, greatly transforming the pharmaceutical market and the power and status of professional medicine.[49] But even before there were new therapies, new knowledge was created in the laboratory and moved through both lay and medical channels to the public. Americans learned new ways of thinking about diet and nutrition, and about the causes of disease.[50]

In the nineteenth century, scientific knowledge was created in two overlapping ways that were particularly relevant to Americans' understanding of food, drugs, and their purity: by the use of instruments and the techniques of chemistry. The most significant new instrument was the microscope, which offered a new way of seeing foods and drugs. With the development of achromatic lenses in the early nineteenth century, this centuries-old tool became practical. By the 1840s, the new lenses were available in the United States, and by the 1850s, the new microscopes were widely available to scientists and physicians.[51] As the microscope became common in industrial,

47. Also called "medical science," the application of scientific knowledge and methods to medicine is sometimes dated from the late nineteenth century, *see, e.g.*, LIEBENAU, *supra* note 37, at 36–41, and sometimes from the mid-nineteenth century, *see, e.g.*, ROTHSTEIN, *supra* note 36, at 249 (tracing beginnings of "scientific medicine" to the introduction of anesthetics). *See also* JOHN E. LESCH, THE FIRST MIRACLE DRUGS: HOW THE SULFA DRUGS TRANSFORMED MEDICINE 4 (2007) (discussing the new drugs as part of the "therapeutic revolution").

48. LESCH, *supra* note 47, at 3-7; JOHN P. SWANN, ACADEMIC SCIENTISTS AND THE PHARMACEUTICAL INDUSTRY: COOPERATIVE RESEARCH IN TWENTIETH-CENTURY AMERICA 19–23 (1988) (describing antitoxins and vaccines); John Parascandola, *The Introduction of Antibiotics into Therapeutics*, *in* SICKNESS AND HEALTH IN AMERICA: READINGS IN THE HISTORY OF MEDICINE AND PUBLIC HEALTH 102, 108–09 (Judith Walzer Leavitt & Ronald L. Numbers eds., 3rd ed., rev. 1997) (describing the post-WWII introduction of antibiotics).

49. STARR, *supra* note 36, at 335–36 (linking the rise in the status of medicine to scientific medicine and describing the postwar boom in the medical profession).

50. For discussion of new popular ways of thinking about diet and nutrition, see RIMA D. APPLE, VITAMANIA: VITAMINS IN AMERICAN CULTURE (1996), and for discussion about causes of disease, see NANCY TOMES, THE GOSPEL OF GERMS: MEN, WOMEN, AND THE MICROBE IN AMERICAN LIFE (1998).

51. James H. Cassedy, *The Microscope in American Medical Science, 1840-1860*, 67 ISIS 76, 77–78, 88 (1976). While the microscope had existed for centuries, the development of achromatic lenses in the nineteenth century greatly broadened the usefulness of microscopes. Glenn Sonnedecker & George Urdang, *Legalization of Drug*

academic, and government laboratories, the newly formed American Society of Microscopists began to publish annual proceedings in 1878,[52] further spreading information and enthusiasm about the use of microscopes in research.

In the post-Civil War decades, the microscope slowly became a tool not just for research, but also for testing, allowing new ways of seeing. Under magnification, adulteration of foodstuffs or botanical drugs became visible, as insect droppings and the intermixture of other plant matter could be seen.[53] By 1876, government researchers were attempting to use the microscope to deal with the vexing problem of distinguishing butter from oleomargarine.[54] One enterprising microscopist even developed what he called an "oleomargariscope," a simple, inexpensive viewing device for courtroom use in prosecutions of violations of the butter laws.[55] While the microscope had broad applicability across both food and drugs, the lactometer, a device for measuring the specific gravity of milk, played a more limited, but important, role in the pure-milk movement. Government officials sought to use the lactometer in field tests of milk as a way to detect watered-down milk. Capitalizing on public concern about milk purity, instrument makers sold inexpensive versions for home use, to allow the housewife to test her own milk.[56]

Microscopes and lactometers offered enhancements to traditional ways of seeing based on the intuitive knowledge of the dairyman or housewife. But chemistry, that is, laboratory analysis of compounds, offered an entirely new understanding of both food and drugs. In the laboratory, any food or drug could be analyzed for its constituents. Any food could be broken down into percentages of fatty acid, protein, and starch. Samples could be compared one to another using such component analysis.

Standards Under State Laws in the United States of America, 8 FOOD DRUG COSM. L.J. 741, 742 (1953).

52. *Proceedings of the National Microscopical Congress: Preliminary Statement* (Aug. 14, 1878), *in* PROCEEDINGS OF THE NATIONAL MICROSCOPICAL CONGRESS AND OF THE AMERICAN SOCIETY OF MICROSCOPISTS (1880).

53. Hart, *supra* note 26, at 13.

54. Thomas Taylor, *Butters and Fats: To Distinguish One Fat from Another by Means of the Microscope*, 7 PROC. OF THE AM. SOC. OF MICROSCOPISTS 128, 128–38 (1885).

55. Thomas Taylor, *A New Pocket Polariscope: Oleomargariscope*, 10 PROC. OF THE AM. SOC. OF MICROSCOPISTS 159, 159–60 (1888). The butter laws, a catchall term to refer to state and federal statutes protecting butter from competition by margarine, are described at PABST, *supra* note 29, at 29–38.

56. OKUN, *supra* note 27, at 44, 62–66.

Both instruments and chemical analysis created a major change in understanding adulteration and purity. Time-honored organoleptic tests could be replaced by analysis, using specialized equipment and knowledge not widely available to the ordinary public. Few households had microscopes,[57] and fewer still had chemical laboratories. With the advent of a new epistemology of purity based on science, the problem of adulteration changed from what it had been in the timeworn battle between crafty seller and canny purchaser. As a national congress convened to address this newly identified problem noted: "Many a housewife if she were a chemist and had the requisite facilities could demonstrate how much of a falsehood and deceit are represented in her pantry."[58] The congress was called because the housewife *lacked* those facilities. What had formerly been a local problem susceptible to lay investigation now required national solutions. New ways of using equipment and expertise needed to be mobilized to eradicate the hidden "falsehood and deceit" in American pantries.

A Senate report accompanying the introduction of a late-nineteenth-century pure-food-and-drug bill (which did not pass) agreed:

> Science has been called upon in the interest of honesty to trace and detect the frauds of scientific dishonesty, and the microscope, test tube, retort, and chemical reagent have opened to view the grave and growing consequences of a greed for gain which is assailing the public health, affecting the pocket of the consumer, and undermining what is so aptly denominated . . . as the very foundation of trade, namely, "Faith in commercial integrity."[59]

Besides "open[ing] to view" frauds of adulteration, science also created a new ontology of food and drugs. By creating a cellular and molecular understanding of food and drugs, these categories were literally recreated. With chemical analysis, food could be identified more precisely—knowing a food in its pure form took on new scientific meaning. Aside from certain hotly debated topics like the adulteration of milk, knowing foods had not previously been much of a problem. Everyone knew, for example, pickles or jellies. The question was whether the product was adulterated with something other than the

57. The extent of popular microscopy in this period is discussed in John Harley Warner, *'Exploring the Inner Labyrinths of Creation': Popular Microscopy in Nineteenth-Century America*, 37 J. HIST. MED. & ALLIED SCI. 7 (1982).

58. Marriot Brosius, Address to the National Pure Food and Drug Congress (Mar. 2, 1898), *in* J. PROC. NAT'L PURE FOOD & DRUG CONGRESS, Mar. 2–5, 1898, at 7, 8.

59. S. REP. NO. 51-1366, at 2 (1890).

expected ingredients. With new possibilities of creating standardized definitions of foods using science, this complacency changed.[60] How much salt or sweetener was used? What sort of sweetener? How ripe was the starting produce? Measuring food at a molecular level could answer these questions. But these answers led to another question: what was the *optimal* answer to such questions? For example, if it was possible to identify the ripeness of the produce used to make a processed food, should that ripeness be specified by regulation? Consumer advocates would increasingly identify knowing foods as a problem, eventually calling for federal regulations setting standards for a multitude of foods, particularly those sold in packaged and/or processed forms.[61] A pickle, it turned out, could be defined and known scientifically.

The question of defining drugs had long bothered pharmacists and doctors, and now science offered new tools for this problem. For drugs derived from the *materia medica*, nature's pharmacy, the question of the standard strength was always an issue, varying not only with intentional adulteration, but also with the place and season of collection, the parts of the plant included, and the method of drying and storage. Even without the aid of the new science, physicians had begun the process of creating standardized definitions of drugs by publishing the first edition of the *United States Pharmacopoeia* (*USP*) in 1820, a dictionary setting forth the standard composition of drugs and directions for their formulation, to guide both doctors and pharmacists.[62] By 1831, control over the periodic revisions to the *USP* had transferred from physicians to a group of pharmacists, who maintained the publication throughout the nineteenth century.[63] In 1846, this first attempt at a standardized formulary was supplemented by the first American version of another aid to standardization, a manual teaching how to use the new science to measure drugs against published standards.[64] The author,

60. H.W. Wiley, *Butter*, 5 SCIENCE 339, 339–40 (1885) (describing the attempt of the Bureau of Chemistry to determine levels of salt, fat, and glycerides in pure butter).

61. In 1936, consumer advocate Ruth deForest Lamb identified this as an on-going problem not yet solved by the 1906 Act. "The food industry . . . offers many serious problems . . . . Except those for butter and few canned foods, there are no legal standards by which to measure the composition and quality of comestibles . . . ." LAMB, *supra* note 10, at ix.

62. Sonnedecker, *supra* note 37, at 103; Sonnedecker & Urdang, *supra* note 51, at 741.

63. OKUN, *supra* note 27, at 25–26; Sonnedecker, *supra* note 37, at 103-04.

64. LEWIS C. BECK, ADULTERATIONS OF VARIOUS SUBSTANCES USED IN MEDICINE AND THE ARTS, WITH THE MEANS OF DETECTING THEM: INTENDED AS A MANUAL FOR THE PHYSICIAN, THE APOTHECARY, AND THE ARTISAN (1846); *see also* OKUN, *supra* note 27, at 6–8.

Lewis C. Beck, a physician and a professor of chemistry at Rutgers College, claimed that the processes he described "may be easily followed even by the tyro in chemistry," although he admitted that some knowledge and experience of chemical testing might be necessary. Even the "tyro" was expected to have a set of instruments and to make up a stock of specialized reagents.[65] Special knowledge and equipment was needed to compare drugs to the published standards.

And those standards were themselves imperfect and contested. The *USP* was only one among many pharmacopoeias, most published in other countries. When a federal law regulating imported drugs passed in 1848, legislators struggled to define a pure drug standard against which to measure the imports. The law required special inspectors to examine imported medicines for "quality, purity and fitness," but permitted inspectors to look to one of five different pharmacopeias to understand what a "pure" drug was, including the *USP* and several foreign publications.[66] Not until the 1906 Act was the *USP* recognized as the sole standard for defining drugs.[67]

The new ontology of food and drugs went deeper than new scientific definitions of known foods and drugs. Chemistry, and the new understanding of substances at a molecular level, allowed for the literal creation of new foods and drugs by recombining their constituent parts. Drugs were no longer limited to the *materia medica* and even foods could be engineered in the laboratory. To the traditional drug categories of botanical, mineral, and mixtures thereof, by the end of the nineteenth century, German chemists were adding chemically purified or synthesized substances newly recognized to have therapeutic properties. The first German breakthroughs came from work on coal tar derivatives used to make synthetic dyes. This work yielded some analgesic and antipyretic substances, including eventually acetylsalicylic acid (aspirin), as well as what came to be called the "sulfa drugs," sulfonamides with anti-bacterial properties.[68] Through chemistry, the pharmacopeia was beginning an expansion by the turn of the twentieth century that would turn into an explosion in the post-WWII decades as drug manufacturers turned to scientific research to identify new drugs.[69]

65. BECK, *supra* note 64, at iii, 279–315.

66. Act of June 26, 1848, ch. 70, 9 Stat. 237 (1848).

67. Pure Food and Drugs Act, ch. 384, 34 Stat. 768 (1906).

68. LESCH, *supra* note 47, at 3-4, 56–61; JAN R. MCTAVISH, PAIN AND PROFITS: THE HISTORY OF THE HEADACHE AND ITS REMEDIES IN AMERICA 64–65, 69–72, 112 (2004).

69. LIEBENAU, *supra* note 37, at 2 (describing "remarkable growth" in the production of drugs after WWII); SWANN, *supra* note 48, at 15–16 (describing an increase in research capabilities in 1920s and 1930s).

The new science also allowed for the development of new foods in the laboratory. Some of the most successful and controversial of the new artificial foods were oleomargarine, a butter substitute first made in France, and glucose, today called corn syrup.[70] By changing what a food might be, these products helped reconfigure the problem of purity from solely a question of adulteration of natural substances to a question of detecting whether a product was a traditional food or an artificial substitute. For example, a product sold as butter could be examined for the presence of extraneous plant and animal matter and also to determine whether the spread was in fact butter, or oleomargarine, or a mixture. While the consumer could detect bits of straw in carelessly made butter, with the introduction of artificial substitutes and without a microscope and a laboratory, she could not know that what she was buying and eating was in fact butter. Seeing and knowing food and drugs was becoming radically different in late nineteenth century America, with changes apparent to laymen and professionals alike.

3. PRE-1906 REGULATION

The new scientific instruments and knowledge helped transform the public perception of the pure-food-and-drugs problem into one that required government regulation and expert intervention. While federal legislative action was a long time coming,[71] even before the 1906 Act there was significant activity on the state level and some examination of food and drug issues by federal agencies.

The connection between scientific and technological advancement and a better food supply was obvious to the first Patent Commissioner Henry Ellsworth, establishing an early link between those concerned with patent policy and with the public health. Ellsworth was appointed under the Patent Act of 1836 to run the new Patent Office. In addition to creating the procedures to implement patent examination, Ellsworth initiated the federal government's involvement in agricultural experimentation, starting a system of correspondence and seed exchange.[72] In 1848, Lewis Beck was hired by the Patent Office to

70. The development of oleomargarine and glucose is discussed *infra* in the text accompanying notes 115 to 124.

71. Exceptions to the nineteenth-century state focus on food and drug laws include the Act of Drug Importation Act of 1848, ch. 70, 9 Stat. 237 (1848), the Tea Act of 1883, ch. 64, 22 Stat. 451 (1883), and federal oleomargarine regulation, Act of Aug. 2, 1886, ch. 840, 24 Stat. 209 (1886).

72. PAT. OFF., REPORT FROM THE COMMISSIONER OF PATENTS, H.R. DOC. NO. 112, at 5 (2d Sess. 1837); LETTER FROM COMMISSIONER OF PATENTS TO THE

analyze foodstuffs, and in his first year, he considered ways of detecting adulteration of wheat.[73] After the Department of Agriculture was created out of the Patent Office in 1862, the Division of Chemistry was formed within the department to continue scientific investigations into various questions related to crops and foods.[74] By 1878, the Division was reporting on food adulteration studies.[75] States also hired chemists to focus on food and crop questions, and the National Association of State Agricultural Chemists became a forum for sharing information about new ways of measuring purity and the new artificial foods.[76]

By 1888, every state and territory except Washington Territory had a pure-food law, a pure-drug law, or both.[77] Chemists in state governments were using their skills to expose adulterations. One of these state chemists, Edgar Richards, argued that while Americans opposed general laws to regulate their food supply, believing themselves smart enough to avoid fraud, science had expanded the abilities of the adulterator as well as that of the chemist, leaving the consumer unable to detect frauds. When Americans realized that fact, Richard proclaimed "the chemists of the country, will have opened to us a new field of usefulness,—a field in which we ought to put forth our best efforts, with the constant aim to maintain the purity and wholesomeness of the food for suffering humanity."[78]

But with even fresh milk crossing state lines from producer to consumer, the best efforts at the state level were unsatisfactory. The pure-food-and-drug problem required not only science, but federal action. The man often credited with the greatest influence in passing the 1906 Act, Harvey Wiley, came from the community of state agricultural chemists.[79] Wiley moved from a position as the State

CHAIRMAN OF THE COMMITTEE ON PATENTS AND THE PATENT OFFICE, S. DOC. NO. 151 (3d. Sess. 1839).

73. LEWIS C. BECK, REPORT ON THE BREADSTUFFS OF THE UNITED STATES, H.R. EXEC. DOC. NO. 59, at 245 (2d Sess. 1848).

74. Hutt, *supra* note 9, at 17–18.

75. ANNUAL REPORT OF THE COMMISSIONER OF AGRICULTURE 6 (1878).

76. YOUNG, *supra* note 7, at 121–24.

77. REPORT OF THE COMMISSIONER OF INTERNAL REVENUE ccix-ccx (listing state laws) (1888). Three states implemented combined food and drug laws: New Jersey (1881), New York (1881), and Massachusetts (1882). OKUN, *supra* note 27, at 154 (citing JESSE P. BATTERSHALL, FOOD ADULTERATION AND ITS DETECTION 268–319 (1887)).

78. Edgar Richards, *Some Food Substitutes and Adulterants*, 15 SCIENCE 86, 90 (1890) (reprint of address of retiring president of Chemical Society of Washington to the Society).

79. STEPHEN WILSON, FOOD & DRUG REGULATION 19–20 (1942); YOUNG, *supra* note 7, at 123.

Chemist of Indiana to the chief of the Chemistry Division in the Federal Department of Agriculture in 1883. From this position within the federal government, Wiley pushed hard for pure-food-and-drug regulation, particularly focusing on food. He used his position to investigate and publicize food adulteration, and published ten volumes of agency reports on the subject before 1906.[80]

Wiley was by no means alone in his efforts. He worked with other scientists, the American Medical Association (AMA), and consumer advocates to lobby Congress for a law. By the turn of the century, the pure-food-and-drug movement was strengthening in the context of faith in scientific expertise as well as social and market transformation. Both the proposed means of regulation and the nature of what was to be regulated were changing with new scientific knowledge and instrumentation. Building a complete picture of this history requires giving up on any simple causal explanation. But there is an additional frame that can be layered over this complicated picture to draw out questions with particular relevance today—the use of intellectual property in markets for food and drugs. This frame helps explain the coalition Wiley was able to harness and the results of this broad effort for federal legislative reform. Opposition to trade secrets became a common thread among reformers, shaping the resulting legislation.

II. FOOD AND DRUG REFORM AS ANTI-SECRECY LEGISLATION

The new science shifted and expanded the perception of the pure-food-and-drug problem at the same time that urbanization and industrialization were making an old problem less tolerable and that professionalization was creating interest groups with particular concerns in the matter. The result was a new focus on ignorance and secrecy as the crux of the problem. What had traditionally been articulated as a problem of adulteration was reconfigured by this shift into a more abstract understanding of the problem, expanding the problems that the pure-food-and-drug movement was attempting to solve and changing the nature of the proposed solution.

Adulteration was still part of the problem, that is, there was still the possibility of harmful foreign matter in foods and drugs. Such substances would never be listed ingredients because they were not a recognized part of products. Adulteration could range from watering milk to cutting a botanical medicine with cheaper plant material to simple dirt and debris in a product due to careless production. Adulteration was the age-old problem, but now, as scientific ways of

80. COPPIN & HIGH, *supra* note 14, at 35–50 (1999); WILSON, *supra* note 79, at 19–20.

knowing required specialized expertise and equipment, it was unsolvable by the consumer despite the attempt to sell lactometers to housewives. Much more subtle levels of adulteration could and should be detected and prevented. Americans would never have the necessary laboratories in their pantries. Lay knowledge, using organoleptic tests, was no longer sufficient to detect purity. The problem of consumer ignorance had to be solved by the enlistment of expertise by the government to inspect and monitor state and national markets in foods and drugs.

There was a new type of consumer ignorance as well, caused by the creation of man-made "artificial" drugs and foods. These comprised a new category that got swept into the pure-food-and-drug movement as products in need of regulation to protect consumers. The existence of these artificial substances encouraged the re-articulation of the adulteration problem into a broader problem of ignorance. The ignorance regarding artificial foods and drugs was a different sort of ignorance. The problem with oleomargarine was not merely whether it contained harmful foreign matter (although it might). Even if the margarine was completely "pure"—free from dirt, debris, or any ingredient not part of the patented production process—a consumer could not tell whether the item for sale was butter or its intentional substitute, oleomargarine. The first-order solution to this problem was not inspection and monitoring, but full disclosure labeling at the point of sale.[81] In order for customers to know what they were buying, whether natural or artificial, they had to be told. Manufacturers could not be allowed to keep the composition of their products secret. Government intervention was needed both to see and to force disclosure—the invisible hand of the market would no longer correct the problem.

The perceived problems that caused the most agitation during the late nineteenth century were proprietary medicines, made with undisclosed ingredients, and the new artificial foods, blended into prepared foods in undetectable ways. In order to encompass these concerns within the pure-food-and-drug movement, reformers had to expand the meaning of "purity" to include both adulteration and undetectable substitution. They did so in part by recasting the purity problem as a secrecy problem. This expansion of the purity problem aligned the purity movement with a preexisting strand of criticism within the medical profession of the use of trade secrets in the drug market, and allowed the enlistment of powerfully motivated allies

81. Inspection might still be used to make sure that labels were accurate, but it was a second order of protection.

among the natural-food producers who were fighting the introduction of artificial foods.

To understand the pure-food-and-drug movement as a campaign against trade secrets, it is necessary to understand the dominant intellectual property regime in the nineteenth-century food and drug markets.

A. The Intellectual Property of Nineteenth-Century Drugs

Within the nineteenth-century food and drug markets, the predominant use of intellectual property was to protect medicines. Patents were not, however, the preferred means of protecting commercial interests in medicines. Despite the use of the term "patent medicines" to describe nineteenth-century nostrums, only a small percentage of medicines were patent-protected in the nineteenth century. The modern pharmaceutical industry with its heavy reliance on the patent system did not emerge until after World War I, that is, after the first federal food and drug act passed, and did not take its modern form until after WWII, after the second federal food and drug act passed.[82] What were widely referred to as "patent medicines" during the nineteenth and early twentieth centuries were usually *not* patented. "Patent medicines" referred to proprietary medicines, medicines sold by only one manufacturer, containing a secret combination of ingredients.[83] A historian of the entrepreneurs who sold such nostrums in the nineteenth and twentieth centuries has argued that only the least savvy sought patent protection for their recipes.[84]

Medicines could be and were patented in the United States from the first days of the republic. Under the patent registration system in place from 1790 to 1836, about seventy-five inventors received patents on medicines, including pills, elixirs, drops, tinctures, and ointments.[85] Samuel Thomson, an entrepreneurial lay practitioner, patented his entire system of medical treatment, and for $20 would grant families a license that permitted them to own and use his book of instructions for compounding and using herbal remedies, several of which he also

82. ALFRED D. CHANDLER JR., SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES 179–80 (2005); SWANN, *supra* note 48, 31–35.

83. *See* discussion in text accompanying *supra* note 45.

84. YOUNG, *supra* note 42, at 40.

85. It is difficult to accurately count patents from this period as all patent office records were destroyed in a fire in 1836. This number was gleaned by Lyman F. Kebler, *United States Patents Granted for Medicines During the Pioneer Years of the Patent Office*, 24 J. AM. PHARMACEUTICAL ASS'N 485, 486–87 (1935) (listing the patents by name).

patented.[86] Although Thomson did not succeed in turning his patents into a fortune, the Thomsonian approach proved quite popular, even leading to Thomsonian medical schools.[87]

As the market for these medicines grew, many purveyors realized that a patent was the most fleeting form of protection, and after the Patent Act of 1836[88] introduced patent examination, possibly the most expensive. The work of preparing a patent application and prosecuting a patent increasingly required paid professional assistance.[89] While a fourteen-year patent was at best renewable for an additional seven years, after 1831 a copyright on the advertising copy on the label, the promotional literature, and flyers could last twenty-eight years, plus a twenty-eight-year renewal term.[90] Better still, a common law trademark in the brand name could last in perpetuity. Further, obtaining a patent meant one certain loss and one possible loss. Each patent required disclosure of the claimed invention, in terms sufficiently specific to allow the public to practice the invention at the expiration of the patent term. Once the patent expired, anyone could make and sell a patented medicine. Further, using a patent to protect a product could also result in the loss of a valuable brand name. If the brand name was the only way to describe the medicine concocted according to the patented formula, the name too fell into the public domain at the end of the patent term and could not be protected as a trademark.[91]

In this legal landscape, many successful sellers of patent medicines relied on trade secret in combination with trademark and copyright to protect the robust market in so-called "patent" medicines.[92] No one but the manufacturer knew what was in the pills, liquids, or ointments sold. When patients bought such medicines as self-treatment, or, as often happened, when physicians prescribed them,[93] neither prescribing doctor nor patient knew what was being ingested. Instead, both relied

86. YOUNG, *supra* note 42, at 46–47, 51, 54.

87. KETT, *supra* note 35, at 100, 106–07; ROTHSTEIN, *supra* note 36, at 125–51.

88. Act of July 4, 1836, ch. 357, 5 Stat. 117.

89. Kara W. Swanson, *The Emergence of the Professional Patent Practitioner*, 50 TECH. & CULTURE 519, 526 (2009).

90. Act of July 4, 1836, ch. 357, 5 Stat. 117 §§ 5, 18; Act of Feb. 3, 1831, ch. 16, 4 Stat. 436.

91. *Centaur Co. v. Heinsfurter*, 84 F. 955, 956–59 (8th Cir. 1898) (denying the patentee a continuing trademark in the Castoria brand name after medicine patent expired).

92. YOUNG, *supra* note 7, at 40. I do not claim that no one sought medical patents after 1836. To the contrary, many Americans did, with approximately five hundred patents to medical compounds issued from 1837 to 1870 (based on an electronic database search of patents by classification number 424).

93. STARR, *supra* note 36, at 129.

upon advertising copy about the powers of the medicine and the recommended dosage. According to its critics, the value of the entire enterprise was built on secrecy:

> Mystery is as necessary to the "patent medicine" maker as it is to the professional magician. . . . The modern proprietary home remedy is mysterious because its composition is essentially secret. Secrecy of composition is to the "patent medicine" maker what the silk handkerchief and the wand are to the vaudeville thaumaturgist. Take away the element of secrecy from the "patent medicine" business and this gigantic monument to human credulity will crumble and decay.[94]

Secrecy allowed the manufacturer to hide, for example, the fact that the medicine contained mostly water, or common household ingredients, or significant amounts of alcohol, the revelation of which, it was argued, would drive away consumers. Doctors and pharmacists further alleged that manufacturers had no compunction about changing the ingredients of a medicine to respond to fluctuations in prices of ingredients, while continuing to sell it under the same packaging, using the secrecy of their formulas to disguise shifting compositions. Businessmen bought and sold trade names rather than secret formulas, patents, or manufacturing know-how as they sought to maximize profits.[95]

Elite regular physicians contrasted proprietary medicines based on secrecy against what they called "ethical" medicines. These medicines were the formulary medicines, known parts of the *materia medica*. These medicines were listed in the *USP* or the *National Formulary*,[96] and, if mixtures, could be compounded by any druggist based on published formulae. They, too, were sold under brand names that could be protected as trademarks, but the brand name identified the manufacturer, not the particular product.[97] These so-called ethical manufacturers who built businesses on supplying doctors and

94. Arthur J. Cramp, *"Patent Medicines": IV. Secrecy and Mystery—The Essentials*, 1 HYGEIA 243 (1923).

95. JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH-CENTURY AMERICA 22 (1967).

96. The *National Formulary* began publication in 1888 as a supplement to the *USP*, providing the formulae for nonproprietary medicines not included in the *USP*, and developed similar status. Sonnedecker, *supra* note 37, at 109.

97. Jeremy A. Greene, *What's in a Name? Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, J. HIST. MED. & ALLIED SCI., Sept. 21, 2010, at 8–9, http://jhmas.oxfordjournals.org/content/early/2010/09/21/jhmas.jrq049.full?sid=004d718c-da48-4298-9f72-606457b3e43e.

pharmacists with consistent, good quality supplies of formulary drugs were a small part of the drug market.[98] By the turn of the twentieth century, as the campaign of regular physicians against proprietary medicines gained strength, the ethical medicines were also defined by their advertisement to physicians, rather than directly to the public.[99]

Regular physicians had long criticized the sale and use of proprietary medicines, even as medical journals accepted advertisements from their manufacturers and many doctors wrote prescriptions for such medicines.[100] The critiques generally fell into three categories: (1) such nostrums were sold for far more than the value of their ingredients, and therefore were a fraud on the public's pocketbook; (2) such nostrums actively harmed their users by containing powerful drugs such as morphine; and (3) such nostrums in no way fulfilled the promises made on their labels and in their elaborate advertisements, like claims to cure cancer, tuberculosis, and syphilis.[101] At best, consumers were being hoodwinked, and at worst, they were poisoning themselves and their children. These arguments were marshaled by maverick reformers and by interest groups most harmed by the sale of proprietary medicines—doctors who lost patients to self-care and druggists who lost sales to other outlets that stocked proprietary medicines next to dry goods.[102] Just like the agricultural interests which objected most strenuously to new artificial foods, the medical interests aligned against proprietary medicines were acting to protect themselves from competition.

For doctors and pharmacists, the campaign against proprietary medicines was also part of professionalization. Pharmacists sought to distinguish themselves as the experts who compounded drugs, and doctors sought to distinguish themselves as experts who prescribed drugs to treat particular patients, relying on their medical knowledge to be specific, rather than offering general cure-alls.[103]

98. Note that while the so-called ethical manufacturers did generally confine themselves to advertising to doctors, they sold their own proprietary medicines, and the distinction between ethical and non-ethical manufacturers was not always clear. MCTAVISH, *supra* note 68, at 46–60.

99. Greene, *supra* note 97, at 8–9. Canny proprietary manufacturers imitated this approach, advertising medicines to physicians, in the hopes of getting physicians to recommend a medicine that the patient could then continue buying without prescription. YOUNG, *supra* note 42, at 159–60.

100. STARR, *supra* note 36, at 127–29.

101. These themes are discussed generally in, for example, ADAMS, *supra* note 7; YOUNG, *supra* note 42, at 67–73, 205–25.

102. OKUN, *supra* note 27, at 26–27 (pharmacists); STARR, *supra* note 36, at 127–31 (doctors and muckrakers).

103. *See* STARR, *supra* note 36, at 134 (discussing the use of authority to prescribe drugs as part of the rising authority and status of the medical profession).

Just as new ways of seeing and knowing through science had transformed the purity problem generally, they transformed the proprietary-medicine problem in ways that helped link this perennial medical complaint with the broader consumer movement for pure food and drugs. The link was the campaign against ignorance through the deployment of science. Science provided the tools to determine the contents of proprietary medicines. Chemical analysis could show which soothing syrups for colicky babies were high in morphine, and which tonics for female troubles were high in alcohol. Reformers emphasized the risks to vulnerable women and children, recounting tales of mothers inadvertently addicting their children to morphine and dedicated teetotalers becoming alcoholics through self-medicating, all without any awareness of the ingredients of the potions they were using.[104] Many were also outraged by the idea that Americans were paying large sums to consume medicines that were largely water, perhaps mixed with other common, harmless ingredients, worth only pennies. New ways of seeing and knowing helped expand the problem beyond the competitive pressures of the medical marketplace. If Americans only knew what they were paying for, they raged, they would stop wasting their money.

None of these arguments had to do with diluting expensive foods and medicines with cheaper imitations or allowing harmful contaminants into powders and tonics. The identified problem with proprietary medicines was a different sort of fraud and deception—convincing Americans that patent medicines were worth the retail price when, in fact, they were good for nothing at all and in some instances were harmful because of the powerful drugs they contained. Patent medicines were "The Great American Fraud."[105] In the first years of the twentieth century, and continuing through passage of the 1938 Act, a coalition of muckraking journalists, the AMA, and ethical manufacturers worked to publicize this fraud, seeking both to persuade Americans to give up self-dosing, and to persuade legislators to replace secrecy with disclosure in the marketplace.[106] The AMA began the

104. *See, e.g.*, ADAMS, *Peruna and the Bracers*, in THE GREAT AMERICAN FRAUD, *supra* note 7, at 12, 13.

105. ADAMS, *supra* note 7, at 1 (reprinting a series of muckraking articles from *Collier's Weekly*).

106. The coalitions in the 1900s and the 1930s were similar, but not identical. JACKSON, *supra* note 12, at 15–21 (outlining lobbying for reform in the 1920s and 1930s); YOUNG, *supra* note 7, at 5 (coalition organized by Harvey Wiley after 1883); *see also* JAMES G. BURROW, AMA: VOICE OF AMERICAN MEDICINE 67–92, 107–31, 252–80 (1963) (summarizing AMA involvement in food and drug campaigns before 1906 and throughout the 1920s and 1930s); James G. Burrow, *The Prescription-Drug Policies of the American Medical Association in the Progressive Era*, *in* SAFEGUARDING

publication of a series of pamphlets to educate the public about patent medicines and conducted a letter-writing campaign on behalf of the 1906 Act.[107] Samuel Hopkins Adams, the journalist who wrote a four-part series in *Collier's Weekly* about patent medicines in 1905, fed information to the congressmen pushing the legislation. The joint goal was to prevent fraud through the abolition of secrecy. As the AMA proclaimed in 1933, describing its on-going work to expose medical frauds: "An intelligent and enlightened consumer is a safe consumer."[108]

Purity in its moral sense was useful here as a rhetorical link between the problems of adulteration and the problems of secrecy—in contrast to pure food and medicines, the proprietary medicine sellers were vending frauds and deceits. As described in *Collier's Weekly*, they were selling "evil."[109] Vendors of pure products, like the pure in heart, had nothing to hide. Knowledge would solve the problem. The journalistic exposés were designed to enlighten the consuming public. Even better would be to require the manufacturers themselves to list their ingredients—replacing mystery with knowledge—and to restrict them in their advertising, labels, and accompanying literature to the pure truth, rather than extravagant claims of cure. The evil was secrecy, and purity would be gained through knowledge.

Despite the public criticism, the numbers of proprietary medicines on the market continued to grow. In 1859, the output of proprietary medicine production was valued at $3.5 million. By 1909, that figure had increased over twenty-fold to about $75 million. In 1905, a trade journal listed twenty-eight thousand such medicines.[110] To fight this evil, the pure-food-and-drug movement had to expand the meaning of "purity" and base its argument on intellectual property grounds, pushing for an abolition of trade secrets in medicines, as well as for standardization and anti-adulteration.

B. Secrecy and Foods

For nearly as long as proprietary medicines have been sold in the United States, doctors have opposed their use as "quackery."[111]

THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL 112, 112–22 (John B. Blake ed., 1970).

107. Morris Fishbein, *The American Medical Association's Work for Consumer Protection,* 1 LAW & CONTEMP. PROBS. 50, 50–51 (1933).

108. *Id.* at 50.

109. Adams's first series of articles was titled "The Nostrum Evil." ADAMS, *supra* note 7, at 3.

110. YOUNG, *supra* note 42, at 109–10.

111. *Id.* at vii (dating the first significant opposition to Jacksonian period).

Identifying non-proprietary drugs as "ethical" and proprietary drugs as "unethical" was only one more aspect of a long campaign to push these wildly popular drugs out of the marketplace. The medical profession became successful in its campaign only after the campaign against proprietary medicines became part of the broadened campaign for purity. The pure-foods movement—the dominant strain of the purity movement through most of the nineteenth century, and the area in which reformers had achieved the greatest success at the local, state, and national levels before 1906[112]—had never focused on intellectual property as a problem in the food market. This changed, however, when the food industry became roiled by the challenges posed to traditional food manufacturers and farmers by artificial foods. The focus on ignorance, secrecy, and the need for consumer information provided common ground between agricultural interests fighting competition from new artificial foods and the medical interests fighting competition from proprietary medicines.

Unlike the century of opposition to proprietary medicines, there was no long tradition of opposition to secrecy in the ingredients of food, in part because there was general consensus about what should be included in standard foods, like bread. While there was protected craft knowledge in the preparation of some prepared foods, such as cheese, wine, and beer, the purity problem had long been one of cheating by replacing what everyone knew should be in a food with low quality, spoiled, or imitation filler. This was not a labeling problem so much as a detection problem—no one proposed that the solution was requiring producers to list chalk or sawdust as ingredients in their bread. The industrialization of production, and the creation of national markets in foodstuffs,[113] provided new opportunities to use intellectual property to commercial advantage in the food market, protecting new methods of processing by patent or trade secret.[114] It was the development of new

112. Historian James Harvey Young's assessment of the dominance of the food aspect of the purity campaign is reflected in the title he chose for his history of the 1906 Act, PURE FOOD, *supra* note 7, at ix. Although Young himself had come to the subject through his research into medicines, he described the movement as "wav[ing] the banner of 'pure food.'" *Id.*

113. *See* CRONON, *supra* note 31, at 97–147, 207–59.

114. Food canning and freezing techniques and equipment were patented, as well as ways of condensing and preserving milk and making margarine. *See, e.g.*, Freezing Pan or Tray for Fish, &c., U.S. Patent No. 386,383 (filed Nov. 30, 1887); Combination Freezing and Preserving House for Fish, Meats, &c., U.S. Patent No. 301,549 (filed Mar. 25, 1884); Canning-Press, U.S. Patent No. 275,906 (filed Feb. 7, 1883); Method of Canning Green Corn, U.S. Patent No. 273,436 (filed Dec. 23, 1882); Improvement in Processes for Canning Food, U.S. Patent No. 223,083 (filed Apr. 5, 1879); Improvement in Processes for Making Artificial Butter, U.S. Patent No. 173,591 (filed Dec. 21, 1875); Improvement in Treating Animal Fats, U.S. Patent No.

"artificial" foods, however, which led some producers to seek regulatory protection from competition. Medical opponents of proprietary medicines and agricultural opponents of artificial foods eventually formed an alliance by casting both their problems as caused by secrecy, as part of the reconfiguration of the purity problem.

Throughout the nineteenth century and into the twentieth century, the artificial foods glucose and oleomargarine caused intense controversy.[115] Glucose, or corn syrup, was a sweetener made from corn, resulting from chemical experiments and first produced in the United States in 1866.[116] Cane sugar had been chemically identified as "sucrose." Glucose was a related molecule, only two-thirds as sweet per unit volume. Depending on the volatile sugar market, it could be a much cheaper, domestic source of sweetener. The United States had long been interested in a domestic alternative to imported cane sugar, either by growing sugar cane in the United States or by the replacement of cane sugar with another sweetener.[117] The industrial production of glucose opened up opportunities for its use in place of cane sugar. It could be used in candies and beverages. It also worked very well as a substitute in honey, maple syrup, and other table syrups, replacing more expensive types of sugars.

The problem with glucose was not so much that it was an impure or harmful foodstuff, although this argument was made.[118] The criticism that proved to have staying power was that the commercial value of glucose was largely as a cheap substitute. Consumers buying "table syrup" or "honey" might find themselves unwittingly purchasing cheaper glucose. Without an obligation to list contents on the label, manufacturers could hide substitution and out-compete producers selling maple syrup and genuine honey.

A similar claim was made against perhaps the most controversial of the new foodstuffs, oleomargarine. A French chemist, Hippolyte Mège Mouriès, invented oleomargarine as a cheap substitute for butter. He attempted to replicate the bovine digestive process in the laboratory, converting bovine fats (beef suet) to a spreadable product with a similar

146,012 (filed Nov. 1, 1873); Improvement in Processes of Preserving and Condensing Milk, U.S. Patent No. 144,310 (filed Oct. 30, 1873); Improvement in Processes for Preserving Milk, U.S. Patent No. 141,878 (filed Feb. 10, 1873).

115. The following discussion draws upon the analysis of these controversies in OKUN, *supra* note 27, at 224–32, 251–83, and YOUNG, *supra* note 7, at 66–94.

116. COPPIN & HIGH, *supra* note 14, at 134–35.

117. DUPREE, *supra* note 33, at 152, 177.

118. YOUNG, *supra* note 7, at 68. A National Academy of Sciences committee, commissioned by Congress to investigate the healthfulness of glucose, found no difference between glucose and sucrose. COPPIN & HIGH, *supra* note 14, at 135; OKUN, *supra* note 27, at 226–32.

chemical composition to butter.[119] He began commercial production in France in 1870 and obtained patents on the process in Europe and America by 1873.[120] The industry rapidly boomed in the United States with thirty-seven licensed manufacturers by 1886.[121] The threat to the dairy industry was obvious and alarming.

Part of the problem was that butter was sold to the public out of large tubs. Tubs of oleomargarine could look almost the same as tubs of butter. If the margarine was colored to match the yellow of summer butter (winter butter was itself artificially colored), the public could not tell the difference. Most dauntingly, chemists themselves could not tell the difference—distinguishing oleomargarine from dairy butter in the laboratory was very difficult.[122]

The problem became much more serious when the meat-packing industry saw a way of using leftover scraps of both pork and cow fat to make margarine, beginning commercial production in 1883. Using different techniques than Mège, the meatpackers produced what they called "butterine," based largely on pig fat, but laced with butter for flavor and texture.[123] Again, the product was almost impossible to distinguish from butter, and much cheaper. This product threatened to swamp the market. Butterine was only one of many alternatives to the original oleomargarine, as many Americans patented their own methods of turning scrap fats into table spreads.[124]

It was no secret that, in response to this new competition, the dairy industry and its allies attempted to eradicate margarine by any means possible. A Wisconsin state official testifying before Congress in 1901, at a time when Minnesota and Wisconsin were major producers of butter and cheese, allegedly stated that he wanted to "drive the oleomargarine manufacturers out of business."[125] The dairy industry waged a multi-pronged campaign against margarine. At the state level, laws regulating oleomargarine were passed in New York,

119. PABST, *supra* note 29, at 18–19.

120. J. van Alphen, *Hippolyte Mège Mouriès*, *in* MARGARINE: AN ECONOMIC, SOCIAL AND SCIENTIFIC HISTORY 1869-1969, at 5, 5–7 (J.H. van Stuyvenberg ed., 1969); Improvement in Treating Animal Fats, U.S. Patent No. 146,012 (filed Nov. 1, 1873), Reissue No. 8424 (filed Aug. 15, 1878).

121. PABST, *supra* note 29, at 20.

122. H.P. Armsby, *Imitation Butter*, 7 SCIENCE 471, 474–75 (1886) (describing various analytic and microscopic tests with drawbacks).

123. YOUNG, *supra* note 7, at 73.

124. At least one hundred and eighty patents were issued to American inventors on butter substitutes between 1866 and 1884. Other manufacturers used vegetable oils to make margarines, including peanut oil, cottonseed oil, and soybean oil. PABST, *supra* note 29, at 19–20.

125. The commissioner later refused to acknowledge this statement. *Id.* at 35 & n.12.

Pennsylvania, and Maryland in the 1870s.[126] New York and Pennsylvania produced 25 percent of the nation's butter at that time.[127] By 1886, multiple states had completely banned the sale and production of oleomargarine. While the constitutionality of such bans was upheld in *Powell v. Pennsylvania*,[128] such state laws had become preempted by a federal law regulating the manufacture and sale of oleomargarine, and taxing its sale, in 1886.[129] Having lost the power to ban margarine state by state, the dairy industry sought more restrictive federal legislation, and did so in part by using the arguments of pure-food reformers.

Like the agricultural opponents to glucose, the dairy industry claimed that margarines were unhealthy—that dirty, diseased, and undesirable fats were used as starting ingredients, and that the chemicals used in the process were incompletely removed from the final product. They also argued, like the cane sugar and honey retailers, that margarine was commercially useful largely to deceive consumers into paying butter prices for a cheaper substitute, stealing customers from dairy butter. The threat from glucose and margarine was not adulteration of these products, but that these artificial foods were themselves adulterants, threatening the purity of pre-existing foods, by trading on the ignorance of the consumer, unable to tell natural from artificial without scientific expertise and equipment. This deceit was described by Wisconsin Senator Robert LaFollette as a direct consequence of producing foods in the laboratory:

> We face a new situation in history. Ingenuity, striking hands with cunning trickery, compounds a substance to counterfeit an article of food. It is made to look like something it is not; to taste and smell like something it is not; to sell like something it is not, and so deceive the purchaser.[130]

Full disclosure was needed at the point of retail sale.

Through this emphasis on avoiding secrecy and alleviating consumer ignorance through accurate labeling requirements, the older agricultural interests (cane sugar and dairy) could link their campaign against the newer agricultural interests (corn processors and meat-packers) to the pure-food movement. The connection drawn between

126. *Id.* at 29–30.

127. *Id.* at 16.

128. 127 U.S. 678, 687 (1888).

129. Act of Aug. 2, 1886, ch. 840, §§ 1–3; *Schollenberger v. Pennsylvania*, 171 U.S. 1, 25 (1898).

130. 49 CONG. REC. 1, app. 225 (1886) (quoted in YOUNG, *supra* note 7, at 66).

the problematic new foods and the pure-food-and-drug movement was the problem with secrecy and ignorance, which required regulatory intervention. Consumers had to be told at the time of sale what they were about to buy—the presence of glucose in table syrups, the percentage of butter and oleo in butterine. The pure food movement thus became in part an anti-intellectual-property-movement, arguing for the abolition of trade secrets in the sale of artificial foods.

The reconfiguration of the purity problem as a problem of consumer ignorance created a stark conflict between those advocating for pure food and drugs through federal regulation to cure ignorance through better labeling on the one hand, and the makers of patent medicines and artificial foods on the other. The manufacturers relied on trade secrets as the basis of their business model; the medical and agricultural interests sought transparency. By tying their quest for federal labeling regulation to a quest for federal scientific expertise to detect adulteration of the sort that would never be exposed by labeling, reformers created a broad umbrella for the pure-food-and-drug movement. Purity was not just the opposite of impurity, but also the opposite of ignorance and secrecy. Exposure was needed, both of what manufacturers knew but hid from their customers, and of what no layperson could detect but what scientific inspectors could find and eliminate.

C. The First Federal Regulation of Food and Drugs

A campaign for comprehensive federal regulation began in earnest in 1879, when the first federal food and drug bill was introduced into Congress. From that year until 1906, such a bill was unsuccessfully introduced into every Congress.[131] In addition to medical professionals, government scientists, and agricultural interests, these decades of reformist agitation also included middle-class women's groups. Female participation ranged from the Women's Christian Temperance Movement (concerned with healthful alternatives to alcohol and the alcoholic content of drinks sold as medicines and tonics), to women's clubs focused on the urban poor (concerned with the quality of food and

131. This discussion draws upon the comprehensive history of nineteenth-century reform efforts in OKUN, *supra* note 27, and YOUNG, *supra* note 7, as well as JACKSON, *supra* note 12. *See also* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984).

milk available), to a nascent consumerist movement (concerned as shoppers with what they bought for their own families).[132]

The text of the 1906 Act as finally passed declared its purpose as "preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors."[133] Because of the limitations of Commerce Clause jurisprudence, it outlawed the interstate shipment of "adulterated" or "misbranded" food or drugs and their manufacture within the District of Columbia and the territories.[134] The Bureau of Chemistry was formally appointed as the entity to examine specimens for violations of the act. "Drug" was defined to cover both established meanings—the formulary drugs listed in the *USP* and *National Formulary* and "any substance or mixture . . . intended to be used for the cure, mitigation, or prevention of disease," that is, the proprietary medicines.[135] Adulteration was defined as the failure of formulary drugs to meet the published standards. Because proprietary medicines were not defined in the *USP* or the *National Formulary*, they could not legally be adulterated, but might be misbranded. Drugs were misbranded if labeled with "any statement . . . which shall be false and misleading in any particular"[136] or if the label failed to state "the quantity or proportion" of a short list of potentially addictive drugs, including alcohol, morphine, cocaine, heroin, chloroform, and cannabis indica.[137] The new foods were considered misbranded if not accurately labeled.[138] They were unlawfully adulterated not only if some harmful substance was mixed in, but also if "any substance" was sold as a substitute "wholly or in part" for the claimed food.[139] Violations were misdemeanors, to be punished by fines not to exceed $500 for a first offense and/or one year's imprisonment.[140]

132. This aspect of the movement is treated comprehensively in Lorine Swainston Goodwin's *The Pure Food, Drink and Drug Crusaders, 1879-1914*. *See* GOODWIN, *supra* note 13, at 2.

133. Pure Food and Drugs Act, ch. 384, § 1, 34 Stat. 768 (1906).

134. § 2.

135. § 6.

136. § 8.

137. *Id.*

138. *Id.* Using the misleading labeling provision, Wiley fought with distillers over the use of "rectified whiskey" and also sought to prevent glucose manufacturers from renaming their product "corn syrup." *See* PABST, *supra* note 29; COPPIN & HIGH, *supra* note 14, at 100–17, 136–41.

139. Pure Food and Drugs Act, ch. 384, § 7, 34 Stat. 768 (1906). There were six distinct ways food could be legally adulterated.

140. § 1.

The proprietary medicine manufacturers quickly reduced the Act's regulatory power to inhibit their business model by winning the case *United States v. Johnson*.[141] In his opinion, Justice Oliver Wendell Holmes declared that Congress had not intended to consider any claims about therapeutic value made on product labels as false or misleading, for such were merely matters of opinion, not susceptible to examination by the Bureau of Chemistry.[142] Thus, manufacturers could continue to fill their labels with broad claims of cure, which was the preferred mode before the Act passed. Congress attempted to strengthen the regulation of false claims of therapeutic value by passing the Sherley Amendment in 1912.[143] This fix, however, failed to fully correct the problem, as the courts interpreted the language of the amendment prohibiting "false and fraudulent" claims to require a showing of intentional falsehood.[144] While the FDA did pursue egregious claims of cure, with so many testimonials as to the value of their products, manufacturers could easily avoid a jury finding of intentional falsehood.[145]

The reformers were thus disappointed by their first legislative triumph as it applied to drugs, both by the continuing ability of manufacturers to make what the medical profession considered to be false claims of cure, and by the failure of the 1906 Act to abolish trade secrets. As long as manufacturers revealed any opiates, and refrained from claiming the inclusion of any ingredients not included, consumers were little wiser than before as to the contents or value. Perhaps not surprisingly, given that Wiley had come from the agricultural scientist community, and that the legislation had passed after a food scandal, the early prosecutions of the FDA were heavily weighted toward foods, rather than toward drugs.[146]

By 1933, the 1906 Act was seen as severely limited by the New Deal brain trusters, and after President Franklin D. Roosevelt took office, FDA officials and law professors quickly drafted an entirely new bill.[147] The new bill had the support of the FDA itself, anxious to

141. 221 U.S. 488 (1911).

142. *Id.* at 497.

143. Sherley Amendment to Pure Food Act, ch. 352, 37 Stat. 416 (1912), *repealed by* Act of June 25, 2938, ch. 675 § 902(a), 52 Stat. 1059.

144. WILSON, *supra* note 7, at 80–82 (reviewing the enforcement problems after the Sherley Amendment).

145. C.W. Crawford, *Technical Problems in Food and Drug Law Enforcement*, 1 LAW & CONTEMP. PROBS. 36, 41–42 (1933).

146. COPPIN & HIGH, *supra* note 14, at 97 (only one hundred and thirty-five out of the first one thousand enforcement actions under the 1906 Act related to drugs).

147. The journal *Law and Contemporary Problems* devoted two early issues to food and drug regulation. The very first issue of the journal in December 1933 was *The*

do more to regulate the markets, as well as of the medical profession. By 1933, the AMA had been publishing pamphlets for about a decade, as well as articles in its new lay magazine, *Hygeia*, seeking to educate the public to shun proprietary medicines and to support legislative reform. More government supervision by the FDA was needed to protect the public.

After two decades of agitation and five years of effort within the FDR administration, the new bill, the Federal Food, Drug, and Cosmetic Act, passed in 1938. Its goals were similar to those of the 1906 Act, to use government expertise to expose what was unknowable to the lay public and to require better labeling to prevent avoidable ignorance. The new Act was much longer and more detailed, as its drafters had sought to close perceived loopholes in the first regulatory scheme. For example, the 1938 Act included medical devices and cosmetics, which the earlier act had ignored.[148] The understanding of misbranding through mislabeling was also made more specific and broader. The Act mandated more specificity and disclosure in both food and drug labels, further limiting, although not eliminating, trade secrets in recipes and formulae.

Foods had to be labeled with the common and usual name of each ingredient, although certain spices and flavorings could be included without disclosure—permitting a zone of secrecy.[149] Further, as advocates had requested, the FDA was required to promulgate food standards for certain foods, creating the grocery equivalent of the *USP*.[150] Standardized foods were exempted from the need to list ingredients, unless the manufacturer added additional ingredients beyond the standard specifications.[151]

All drugs had to bear a label with "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count" as well as the name and address of the manufacturer or

Protection of the Consumer of Food and Drugs. In numerous articles, New Dealers made their critique of the existing law and set out their proposed changes. *See, e.g.*, Mitchell Salem Fisher, *The Proposed Food and Drugs Act: A Legal Critique*, 1 LAW & CONTEMP. PROBS. 74, 74–75 (1933). The Winter issue of 1939 celebrated and explained the new act. One of the New Dealers involved in the five-year fight for passage wrote a legislative history of the new bill. David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2, 2–3 (1939); *see also* JACKSON, *supra* note 12, at 24–27.

148. Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(h)-(i), 52 Stat. 1040 (1938).

149. § 403(i).

150. § 401.

151. § 403(g).

distributer.[152] If a drug contained any listed narcotic—and the list was expanded to include marihuana and peyote—the label must include the statement: "Warning—May be habit forming."[153] Most significantly, for any non-formulary drug, the "common or usual name" of each active ingredient had to be listed on the label.[154] Finally, many ingredients of proprietary medicines would be revealed to the public, even if the exact formulae were not. With the 1938 Act, secrecy in the food and drug markets was reduced both by labeling and by the enlistment of scientific expertise.[155]

Yet in the very stimulus for the bill's final passage, the sulfanilamide tragedy, lay indications that the focus on disclosure of trade secrets was inadequate. Even if each bottle had been clearly labeled "diethethylene glycol," how could patients have used that information? The 1938 Act contained additional provisions that marked the beginning of a turn from a narrow focus on disclosure toward paternalistic interventions to preclude unsafe decisions by consumers. The Act required drug manufacturers to provide "adequate directions for use" and "adequate warnings against use . . . where . . . use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application."[156] These requirements, very familiar to present-day users of over-the-counter medications, were designed to decrease the perceived danger of self-medicating with unfamiliar, powerful substances by holding the manufacturer responsible for "adequately" describing proper use and warning against dangerous uses. A label disclosing the inclusion of alcohol or morphine would warn against dangers well-discussed for decades in temperance materials. Drugs within the *materia medica* had been used by people for decades, if not centuries. They were familiar. A disclosure of sulfanilamide did not occur within a similar social context of experience. The likely effects of use and overuse were not within shared cultural knowledge. Later in 1938, the FDA used its regulatory authority to allow manufacturers to avoid the requirement to include directions for use and warning against misuse by labeling a medicine for use by prescription only.[157] This provision was the beginning of a legal division between prescription medicine and over-the-counter

152. § 502(b).

153. § 502(d).

154. § 502(e).

155. Cavers, *supra* note 147, at 28–41 (explaining and celebrating the bill as an improvement over the 1906 Act).

156. Federal Food, Drug, and Cosmetic Act § 502(f).

157. §§ 502(f), 503 (quoted and discussed in TEMIN, *supra* note 5, at 46–47).

medicine, a new way of segmenting the drug market that would come to swamp the distinction between proprietary and formulary drugs.

III. MEDICAL PATENTS

From a contemporary perspective, we might assume that the purity campaign, as a campaign against trade secrets, would embrace patents as a better intellectual property regime. Patents are often understood as a complementary choice to trade secrets, offering a strong limited-term monopoly in exchange for public disclosure. Today, we are very familiar with the arguments for the use of patents to protect pharmaceuticals—patents allow a period of exclusive sales during which time the originator of a new medicine reaps monopoly pricing as a just reward for a large investment in research and development, providing the necessary reward to incentivize the risky and expensive process of drug development. Once the drug comes off patent, other manufacturers can make and sell the same drug, causing the price paid by consumers to drop.[158]

In 1938, as the world of laboratory-created drugs was just emerging, this argument was not yet dominant. Instead, Americans, and particularly American doctors and pharmacists, were familiar with another argument regarding patents and medicines, an argument that had persisted over the previous century. This older argument described "medical patents"—a term which lumped together any patents to medicines, methods of treatment, and medical devices—as unethical. This argument remained convincing to many through the period of the pure-food-and-drug movement. As a consequence, the turn-of-the-century focus on the regulatory elimination of trade secrets was not accompanied by any embrace of patents as a preferred form of intellectual property protection.

Yet, the new scientific ways of knowing had changed the landscape of both trade secrets and patents within the drug market. Chemistry made keeping secrets from competitors much more difficult. The proprietary medicines could be analyzed and their contents publicized. Manufacturers did not even necessarily need to do this work themselves; the AMA did some of this analysis and publication as part of its campaign against secrecy.[159] Further, as trade secrets were becoming less meaningful, medical patents were increasing in number

158. *See generally* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 59–62, 142–55 (2009).

159. Cramp, *supra* note 7, at 51–53 (describing the project of analysis and publication); *see also* 3 CRAMP, NOSTRUMS AND QUACKERY AND PSEUDO-MEDICINE, *supra* note 10, *passim* (examples of publicizing ingredients).

and significance. New chemical compounds were patentable, whether their use was in industry or in medical treatment, and the pharmaceutical firms saw no reason to forego the practices that were becoming routine in the chemical industry. In the aftermath of its battle against trade secrets, within the changing landscape of the drug market, the medical profession reevaluated the worth of medical patents. In the decades after 1906 and 1938, the medical profession performed an about-face with respect to patents, giving up its former opposition and instead seeking to use them to advance professional ethics. This change of approach was a tactic in a losing battle to maintain the upper hand over the pharmaceutical market that doctors had thought they were gaining with the new federal regulation. Patents instead became a powerful instrument of control used by the pharmaceutical manufacturers.

A. Opposition to and Embrace of Medical Patents

At the founding meeting of the AMA in 1847, the group of physicians gathered to create the first national medical association also unanimously passed the first formal code of medical ethics. The AMA Code of Ethics characterized both medical patents and the use of any secret medicines as "derogatory to professional character" and forbad patenting of surgical instruments or medicines by physicians.[160] It was derogatory to the profession because the only purpose of a patent was to protect trade in a medicine, and as a liberal profession, medical doctors dealt in advice, not in goods, and would lower professional standards by entering trade. It was also derogatory to the profession because patents hindered the public health by allowing monopoly pricing of cures, making them more difficult for patients to purchase, and by preventing other doctors from carrying out further investigation of a novel medicine.[161] Put into modern language, the ethical problem shared by both trade secrets and patents was that both privatized the

160. CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION, ch. II, art. I, § 4 (1847), *reprinted in* THE AMERICAN MEDICAL ETHICS REVOLUTION: HOW THE AMA'S CODE OF ETHICS HAS TRANSFORMED PHYSICIANS' RELATIONSHIPS TO PATIENTS, PROFESSIONALS, AND SOCIETY 324–28 (Robert B. Baker et al. eds., 1999) [hereinafter THE AMERICAN MEDICAL ETHICS REVOLUTION].

161. Joseph M. Gabriel, *A Thing Patented Is a Thing Divulged: Francis E. Stewart, George S. Davis, and the Legitimization of Intellectual Property Rights in Pharmaceutical Manufacturing, 1879-1911*, 64 J. HIST. MED. & ALLIED SCI. 135, 139–42 (2009) (discussing the underlying medical ethos); F.E. Stewart, *Is It Ethical for Medical Men to Patent Medical Inventions?*, 29 J. AM. MED. ASS'N 583, 583-87 (1897), *reprinted in* 278 J. AM. MED. ASS'N 816b, 816b (1997) (summarizing long-standing arguments against patents).

commons. While secrecy was harmful, the openness of a patent in no way removed the ethical taint of propertizing medical knowledge, and presumably, planning to exploit that private property for private gain.[162] Knowledge useful for healing should never be privately owned or exploited.

The elite pharmacists, who were also seeking to professionalize, shared this attitude. The Philadelphia College of Pharmacy created a code for its members in 1848 stating that "no member of this College should originate or prepare a medicine, the composition of which is concealed from other members, or from regular physicians" and espousing the position that "any discovery which is useful in alleviating human suffering . . . should be made public for the good of humanity."[163] The American Pharmaceutical Association followed suit in 1852, enjoining its members to "uphold the use of the Pharmacopoeia," avoiding "secret formulae and . . . a quackish spirit."[164]

The AMA tried to convert its opposition into patent policy. One of the early members of the AMA, Dr. Thomas Edwards, was also a congressman from Ohio,[165] and in 1849 he authored a report to a House of Representatives committee on the advisability of amending patent law to exclude compound medicines from patentability. His report advised the passage of legislation to halt this great and growing evil.[166] The report also noted that many state medical societies prohibited their members from patenting medicines and deplored any trained physician who would allow "avarice and cupidity" to overcome his duty to share any knowledge of treatment with the world at large.[167] The proposed bill, however, did not pass.[168]

As scientific medicine gained ground, the medical opposition to medical patents gathered new arguments. Scientific progress was made by publishing results to be used and tested by others. In the cumulative

162. Gabriel, *supra* note 161, at 142 (discussing the disparagement of trade secrets and patents as posing the same evils).

163. Charles H. Lawall, *Pharmaceutical Ethics*, 10 J. AM. PHARMACISTS ASS'N 895, 897 (1921).

164. AMERICAN PHARMACEUTICAL ASSOCIATION CODE OF ETHICS (1852), *reprinted in* ROBERT A. BUERKI & LOUIS D. VOTTERO, ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE 193-94 (2002). The 1852 Code was first revised in 1922, and the 1922 Code of Ethics included the obligation to "discourage the use of objectionable nostrums." AMERICAN PHARMACEUTICAL ASSOCIATION CODE OF ETHICS (1922), *reprinted in* BUERKI & VOTTERO, *supra*, at 195.

165. Gabriel, *supra* note 161, at 143.

166. H.R. REP. NO. 30-52 (1849).

167. *Id.* at 30 (1849).

168. H.R. REP. NO. 30-755, at 1 (1848).

process that was the scientific production of better medical understanding, both secrecy and patents were unscientific attempts to stifle the necessary circulation of information. Medical patents, then, were not only unprofessional, but unscientific.[169]

While the original AMA Code of Ethics caused some controversy within the profession in the 1880s,[170] the AMA maintained the anti-patent language. In 1898, Congress appointed a commission to study possible revisions to the U.S. patent and trademark laws. In public hearings, the committee heard comments urging an exclusion of medicines from patentability.[171] The Committee failed to recommend such a change,[172] but the medical opposition continued. In 1903, the AMA replaced its Code with the Principles of Medical Ethics, but it again condemned patents as "derogatory to professional character," along with the use of "secret medicines," because concealment "is inconsistent with beneficence and professional liberality."[173] The passage of the 1906 Act was not marked by any moderation in the stance of organized medicine against medical patents. Rather, even after the first successful federal assault on medical trade secrets, the opposition of the medical profession to medical patents continued into the 1930s, and any doctor who kept a new medicine secret or patented it did so at the risk of his or her reputation as an ethical medical professional.[174]

Despite this persistent opposition, the medical profession failed to influence patenting behavior in the drug market.[175] As discussed above, after 1836, patents were not an attractive option for maximizing profits in a medical cure. But if and when the maker of a proprietary medicine

169. F.E. Stewart, *On Patent and Trademark Laws*, *in* PROC. AM. PHARM. ASS'N 132, 134 (1889). Note that Stewart personally believed that patents, although not trade secrets, could support the scientific advance of therapeutics. *Id.* at 144.

170. John Harley Warner, *The 1880s Rebellion Against the AMA Code of Ethics: "Scientific Democracy" and the Dissolution of Orthodoxy*, *in* THE AMERICAN MEDICAL ETHICS REVOLUTION, *supra* note 160, at 52.

171. S. DOC. NO. 56-20, at 31–32 (1898).

172. *Id.* at 35.

173. AMERICAN MEDICAL ASSOCIATION, PRINCIPLES OF MEDICAL ETHICS, ch. II, art. I, § 8 (1903), *reprinted in* THE AMERICAN MEDICAL ETHICS REVOLUTION, *supra* note 160, app. D, at 335–39. The Philadelphia College of Pharmacy also retained its opposition to secrecy and the exploitation of any new discovery for the public good in its 1900 Code. Lawall, *supra* note 163, at 899.

174. *See infra* text accompanying notes 244–52.

175. The Code, and the Principles, also tried to keep doctors from prescribing, endorsing or selling proprietary medicines—and in this, it is widely conceded that the profession failed. Even the pages of the AMA's own new journal, the *Journal of the American Medical Association,* founded in 1883, were filled with advertisements for nostrums. STARR, *supra* note 36, at 129.

found such a patent to be worthwhile, the laws allowed her to obtain it. Neither in 1849 nor thereafter did the AMA succeed in removing medicines from patentability. And Americans did obtain medical patents, by the hundreds.[176] Even the ability of the AMA to sanction its own members was a weak form of enforcement. The AMA was limited to refusing membership to any doctor who held a patent—and indeed, it reportedly refused to seat a doctor at its annual meeting in 1896 who had applied for, but not yet received, a patent.[177] The doctor, however, was free to continue to practice medicine and to wield his patent as he saw fit. The opposition may have inhibited some doctors from seeking patents, but certainly not all, and presumably had little effect on lay people.

For the most part, however, during the decades that the medical profession worked in coalition to pass federal food and drug laws, the failure to eliminate medical patents caused little harm. The proprietary industry relied on trade secrets, not patents.[178] The patents granted usually did not create monopoly power over effective new cures because there were few effective cures to commercialize. Even as medicine became more scientific, the promise of cures greatly outstripped their development by medical researchers. Because there were so few drugs worth patenting, the elite of the medical profession were able to find one ally in their campaign against medical patents within the drug market itself—the ethical pharmaceutical manufacturers. Not only did these manufacturers concentrate on the manufacture and sale of known, fully labeled drugs, but they did not patent their medicines. Formulary drugs, as known substances and mixtures, were not patentable. These firms included many of what would become the research-based pharmaceutical companies of the twentieth century, including Merck, Smith Kline & Co., Parke Davis, Eli Lilly, John Wyeth, Upjohn, and Sharp & Dohme.[179] The founder of another ethical company, Edward Squibb, a Navy doctor turned drug

176. *See, e.g.*, Improvement in Liniments for the Cure of Rheumatism, U.S. Patent No. 110,288 (dated Dec. 20, 1870), and Improvement in Healing-Salves, U.S. Patent No. 109,599 (dated Nov. 29, 1870). These are two of the over five hundred patents described at *supra* note 92. Note that patent records do not indicate the occupation of the inventor, so it is not possible to determine how many of these patents were obtained by doctors.

177. SWANN, *supra* note 48, at 34.

178. Stewart, *supra* note 169, at 132, 144–45. There is also anecdotal evidence that the patent office deliberately tried to keep the number of medical patents low by examining them strictly. Karl Fenning, *Patent Medicine Legislation*, 24 J. PAT. OFF. SOC'Y 210, 210–11 (1942); *see also* LIEBENAU, *supra* note 37, at 8.

179. CHANDLER, *supra* note 82, at 182–83 (discussing the twentieth-century development of the same companies); LIEBENAU, *supra* note 37, at 34 (discussing late-nineteenth century companies).

manufacturer, became a consistent, strong voice for "ethical" pharmaceuticals, campaigning both against drug patents and trade secrets and for pure food and drugs, helping to draft the New York and New Jersey state food and drug laws.[180] For both doctors and ethical manufacturers, the use of patents and trade secrets distinguished the proprietary manufacturers from those manufacturers who respected the ethics of the medical profession. The campaign against unethical, "patent" medicines was a campaign to reduce competition for both doctors and the ethical pharmaceutical manufacturers.

There was a moment of possible change in the patent laws as the Unites States began to feel the effects of WWI in Europe. Just before the United States entered the war, the first shipments of the patented anti-syphilis drug Salvarsan reached the United States. A controversy erupted as supplies remained very limited due to the British blockade of Germany and the inability of the patent licensee to get American production up to desired levels. Another company challenged the patent by beginning production.[181] Salvarsan was only one of many chemicals and pharmaceuticals that Americans found hard to obtain during the war and were legally blocked from manufacturing because of patents. In 1916 and 1917, some Americans again pushed for patent reform with an emphasis on eliminating medical product patents altogether. In 1916, Charles Paige, a representative from Massachusetts, introduced a bill to do so, which was heralded in the pages of the *Journal of the American Pharmaceutical Association*.[182] Instead, Congress passed a bill allowing the executive abrogation of patents controlled by the enemy, categorizing the problem as German patents rather than medical patents.[183] By 1919, the war was over, the Paige bill was dead, and its demise was heralded by the American Drug Manufacturers Association.[184]

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180. LAWRENCE G. BLOCHMAN, DOCTOR SQUIBB: THE LIFE AND TIMES OF A RUGGED IDEALIST 264–81 (1958) (recounting Squibb's life and describing his advocacy for pure-food-and-drug laws); YOUNG, *supra* note 7, at 15-18, 61-63.

181. LIEBENAU, *supra* note 37, at 113-15.

182. H.R. Bill No. 11967, 64th Cong., 1st sess. (1916), F.E. Stewart, *A Discussion of the Paige Bill, Relating to a Proposed Revision of the Patent Law*, 6 J. AM PHARMACEUTICAL ASS'N. 122, 122 (1917). *See also* J.W. England, *The Product-Protection of Chemical Compounds*, 6 J. AM. PHARMACEUTICAL. ASS'N 120, 121 (1917) (advocating for abolition of product patents).

183. Act of Oct. 6, 1917, ch. 106, 40 Stat. 411, 420–22 (repealed 1946).

184. L.E. Sayre, *Patent Laws in Regard to the Protection of Chemical Industry*, 30 TRANSACTIONS KAN. ACAD. SCI. 39, 43 (Apr. 18, 1919–Feb. 19, 1921) (discussing a letter from a "large" drug manufacturer). In 1916, a meeting of the National Drug Trade Conference had determined that generally retailers favored process patents and manufacturers favored product patents. *Report of Committee on Patents*, 49 PHARMACEUTICAL ERA 44, 44 (1916).

During the war, the AMA began to show signs of changing its official opposition to all medical patents. In 1914, the AMA had adopted a resolution allowing its Board of Trustees to accept "patents for medical and surgical instruments and appliances . . . as trustees for the benefit of the profession and the public" without either the AMA or the inventor receiving any financial benefit.[185] In 1918, the AMA accepted responsibility for a patent covering thyroxin, a hormone discovered at the Mayo Clinic.[186] The Clinic assigned the patent to the AMA to manage for the good of medicine. This attempt foundered due to lack of agreement among the AMA membership about whether medical patents should be allowed at all.[187] Remembering that failure, the AMA refused to accept assignment of a patent for scarlet fever antitoxin in 1924.[188] Despite these initial negative experiences, the AMA's official position toward patents changed rather quickly during the late 1930s. While patents had not been seen as an attractive alternative to trade secrets during the campaign for pure food and drugs, by the culmination of the anti-secrecy aspects of that campaign in the 1938 Act, the previous joint disparagement of these two forms of intellectual property was being replaced by an AMA endorsement of patents.[189] By 1937, the editor of the AMA's journal, Morris Fishbein, was editorializing and speaking on behalf of the establishment of a non-profit corporation to hold all medical patents, to license inventions to manufacturers, and to collect reasonable royalties for the discoverers.[190] Fishbein and other patent advocates within medicine argued that patents, viewed correctly, could be ethical tools, rather than the hallmark of unethical exploitation of a vulnerable public.[191] Fishbein

185. Morris Fishbein, *Are Patents on Medicinal Discoveries and on Foods in the Public Interest?*, 29 INDUS. & ENGINEERING CHEMISTRY 1315, 1317 (1937) (quoting a 1914 AMA resolution).

186. Charles Weiner, *Patenting and Academic Research: Historic Case Studies*, 12 SCI. TECH. & HUM. VALUES 50, 53 (1987).

187. *Id.* at 53. The thyroxin patent ended up under the control of the University of Minnesota. Fishbein, *supra* note 185, at 1316. Despite this experiment, the AMA's council on pharmacy and chemistry still urged that "in many instances the patent law . . . is contrary to the best interest of the public . . . as concerns health and prosperity." Sayre, *supra* note 184, at 41–42.

188. Weiner, *supra* note 186, at 53.

189. Note, of course, that AMA official positions do not reflect the views of all physicians, merely the majority of voting members at a meeting.

190. Fishbein, *supra* note 185, at 1318.

191. Note that Charles Weiner has traced a similar decline in opposition to patents by academic researchers during this period. Weiner, *supra* note 186, at 50–51; *see also* Grischa Metlay, *Reconsidering Renormalization: Stability and Change in 20th-Century Views on University Patents*, 36 SOC. STUD. SCI. 565 (2006) (discussing patent

argued that there was "need for some revision in the medical point of view concerning medical patents."[192] In fact, Fishbein stated, "[t]he act of securing a patent is not in itself unethical."[193] In 1939, Fishbein was joined by others within the AMA in publicly advocating medical control of medical patents.[194] The postwar intellectual property regime which has become familiar to contemporary critics of the pharmaceutical and food industries was being created with much more medical approval than might have been anticipated only a decade earlier.

B. Patenting the New Drugs

During the same decades as the battle against secrecy in food and drugs was finding success at the federal level, the drug market was undergoing profound changes. As an international community of chemists gained the ability to create artificial drugs in the laboratory, science was changing not only the epistemology of purity, but the very ontology of drugs and disease. During most of the nineteenth century, the pharmaceutical commons was well known and well used. There were no therapeutic breakthroughs to be monopolized. It was the same *materia medica* that had been available to Americans since colonization—Old World botanical and mineral drugs supplemented by New World discoveries.[195] But using the new scientific ways of knowing and seeing, researchers were contemplating not only new "artificial" drugs, thus expanding the traditional commons, but a new understanding of the very purpose of drugs, expanding their potential value, both therapeutically and commercially.

According to Galenic theory, educated physicians had always treated the symptoms of an individual patient.[196] Each patient was considered with respect to his or her age, constitution, and environment, and the skill of the physician involved varying treatment day by day, even hour by hour, to restore the imbalance that underlay ill health.[197] Only "quack[s]" claimed to treat diseases with a one-size-

debates within the American Association for the Advancement of Science and the American Chemical Society).

192. Fishbein, *supra* note 185, at 1317.

193. *Id.* at 1318.

194. American Medical Association, *Conference on Medical Patents*, 113 J. AM. MED. ASS'N 327, 327–36, 419–27 (1939).

195. LIEBENAU, *supra* note 37, at 11–15.

196. Erwin H. Ackerknecht, *A Short Survey of Drug Therapy Prior to 1900*, *in* SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL 51, 51–52 (John B. Blake ed., 1970).

197. LIEBENAU, *supra* note 37, at 13-14; WARNER, *supra* note 39, at 58–59; YOUNG, *supra* note 7, at 27–28.

fits-all cure.[198] Throughout the nineteenth century, this traditional model of disease and treatment was in tension with the new ways of knowing through what has been described as a "therapeutic revolution" based on experimental or scientific medicine, in which knowledge generated in laboratories was used by scientists and doctors to reconfigure American understanding of both disease and treatment.[199] Under the new germ theory, disease was caused by an external factor, a germ, and if so, could be treated in uniform ways, perhaps with specific drugs. The new drugs were not only new compounds, but could be used in new ways, across many patients, based on new understandings of therapeutic efficacy.[200]

This promise of chemistry was tantalizing. There was a considerable lag, however, between promise and reality. The germ theory of disease, while supporting sanitarians in public hygiene measures, largely provided an explanation for infectious diseases and epidemics without offering any cures.[201] Some early drugs were effective, notably antipyretics and analgesics, but treated symptoms rather than diseases. Paul Erlich, a German scientist and the originator of Salvarsan, the first efficacious treatment for syphilis, famously described the goal of chemotherapy as a "magic bullet" of one drug to knock out each disease.[202] Salvarsan was marketed beginning in 1910,[203] and Erlich predicted the arrival of the new therapeutics by 1915, but it was not until the late 1930s that such drugs began to come into use, and only after WWII that a second "therapeutic revolution" occurred in which not just the theory of treatment, but its actuality, changed.[204]

In the decades before WWII, however, there was a trickle of new drugs. These drugs symbolized a new, expanding commons, populated by much more valuable drugs. The scientific origins of the new drugs meant that they were coming out of laboratories, staffed by scientists

198. WARNER, *supra* note 39, at 60–61.

199. The "therapeutic revolution" has been discussed in various aspects by numerous historians. *See, e.g.*, THE THERAPEUTIC REVOLUTION: ESSAYS IN THE SOCIAL HISTORY OF AMERICAN MEDICINE (Morris J. Vogel & Charles E Rosenberg eds., 1979). The phrase is also used to refer to the later introduction of effective, laboratory-based drugs. *See, e.g.*, LESCH, *supra* note 47, at 4.

200. John Harley Warner, *From Specificity to Universalism in Medical Therapeutics: Transformation in the 19th-Century United States*, *in* HISTORY OF THERAPY: PROCEEDINGS OF THE 10TH INTERNATIONAL SYMPOSIUM ON THE COMPARATIVE HISTORY OF MEDICINE – EAST AND WEST 193-224 (Yosio Kawakita, Shizu Sakai & Yasue Otsuka eds., 1990).

201. TOMES, *supra* note 50, at 6.

202. LIEBENAU, *supra* note 37, at 110–11.

203. For a discussion of the chemical work that led to the introduction of the anti-syphilitic drug in 1910 and 1912, see *id.* at 19.

204. LESCH, *supra* note 47, at 15 (describing Erlich's prediction).

and, occasionally, doctors. While these laboratories could be located within the academy, they were also located within companies, as part of the new wave of industrial research.[205] As Fishbein noted in 1937, "pharmacists, chemists, biochemists, physicists, or physiologists" involved in discovery "are not inhibited by such principles of ethics as control the medical profession."[206] There was no value in marketing such drugs as trade secrets, as their introduction would expose their composition to chemical analysis and quick copying. With the new drugs, the spurned medical patent came back into vogue, used by a pharmaceutical industry just beginning the transformation into its modern form. By the mid-1920s, the so-called "ethical" drug companies began to embrace the idea of generating medicines in the laboratory and began to patent these new drugs, blurring the traditional line between patent medicines and formulary drugs.[207]

The landscape in which the medical about-face regarding patents occurred was not only the new regulatory regime represented by the 1938 Act, but this new world of therapeutic approaches, scientific medicine, and a new type of medical patents, creating monopolies over efficacious drugs. This new world of drugs and drug patents offered at least three models of the development of artificial drugs and the use of patents in their commercialization, all reasonably successful in terms of improvements to public health. These models are exemplified by the antipyretics, insulin, and Vitamin D.

1. INDUSTRIAL LABORATORIES AND ANTIPYRETICS

Some of the first new drugs came out of German industrial chemical firms. The German chemical industry had been a sophisticated user of the patent system in Germany and elsewhere before its scientists turned their attention to medicines.[208] Early commercial success with artificial dyes provided resources and enthusiasm for further industrial research, and chemists soon discovered that some of the same compounds used by medical researchers to dye tissue samples because

205. LIEBENAU, *supra* note 37, at 4–5; SWANN, *supra* note 48, at 6–7, 15. For the emergence of biochemistry as a new discipline of applying chemical knowledge to biological questions, see KOHLER, *supra* note 34, at 100–05.

206. Fishbein, *supra* note 185, at 1317.

207. LIEBENAU, *supra* note 37, at 8. This line was always more theoretical than actual. All the so-called ethical manufacturers were interested in making a profit, and walked close to or over the line against trademarks, advertisement, and secrecy. MCTAVISH, *supra* note 68, at 48–58. Further, Dr. Stewart had been advocating for the use of patents by ethical manufacturers since the 1880s. Gabriel, *supra* note 161, at 137, 149–150, 154, 169.

208. MCTAVISH, *supra* note 68, at 67–68.

of their selective uptake by cellular components also had effects on living organisms, which might be useful to treat symptoms, if not to cure diseases.[209] As the Germans developed and introduced a series of artificial antipyretics (fever-reducers) between 1884 and 1887, most came into the American drug market under patent protection.[210] While patented, the drugs otherwise appeared to be more like "ethical" preparations than "patent medicines": they were clinically tested before general introduction, and the results were discussed in medical journals.[211]

More importantly, they seemed to work. As Lyman Kebler, Chief of the Drug Laboratory of the Bureau of Chemistry at the U.S. Department of Agriculture, noted: "The great desideratum of the medical profession has been a safe, effective and inexpensive antipyretic."[212] American doctors embraced these drugs, although not without some note of the patents.[213] Because they were patented, the new drugs were not included in the 1890 edition of the *USP*.[214] Most particularly, Americans noted that Germans were able to monopolize manufacturing by patenting the chemical compound itself in the United States, even though product patents on medicines were not permitted in Germany. The monopoly pricing of the new drugs under patent protection in the United States, relative to pricing in other countries, led to a gray market in imported, and sometimes adulterated, antipyretics.[215] The opposition to this practice was part of the rationale for Paige's failed bill in 1916, attempting to amend the patent law to exclude medicines, although not the processes for making them, from

209. LESCH, *supra* note 47, at 4, 56–61.

210. MCTAVISH, *supra* note 68, at 72–75. One of the most successful of these early drugs, phenacetin, was the subject of several unsuccessful patent challenges. *Maurer v. Dickerson*, 113 F. 870, 870 (3d Cir. 1902); *Farbenfabriken of Elberfeld Co. v. Harriman*, 133 F. 313, 313-14 (D. Mass. 1904).

211. MCTAVISH, *supra* note 68, at 72–75. The refusal of medical journals to publish articles about patent medicines is discussed by Stewart, *supra* note 169, at 144–52 (discussing how only articles on ethical pharmaceuticals were published in medical journals).

212. Lyman F. Kebler, *Phenacetin: History, Patent, Methods of Manufacture and Chemical Constitution*, *in* PROCEEDINGS OF THE AMERICAN PHARMACEUTICAL ASSOCIATION AT THE 51ST ANNUAL MEETING 365, 368 (1903).

213. MCTAVISH, *supra* note 68, at 78 (stating that the drugs had become "too useful to ignore").

214. Gabriel, *supra* note 161, at 158–59.

215. *Farbenfabriken*, 133 F. at 313-14 (defendant in a patent infringement suit was a pharmacist accused of selling gray-market phenacetin); *see also* Kebler, *supra* note 213, at 373 (describing cross-border smuggling of phenacetin).

patentability. The draft bill specifically excluded from patentability "coal-tar dyes or colors," the source of the new German medicines.[216]

The new drugs were even more enthusiastically embraced by patients, who could dose themselves by purchasing the new drugs by name, or within proprietary mixtures, as the proprietary manufacturers incorporated the new drugs into their secret mixtures.[217] The new drugs were efficacious against fevers and against headaches, offering one of the only effective treatments of this age-old malady. They also had powerful side effects, including depressing the action of the heart, sometimes causing fainting. With some reason, therefore, doctors worried about patients dosing themselves with the new drugs, lending support to their long-standing desire to replace self-medication with medically supervised treatment. The risks of the new drugs were highlighted by the sulfanilamide scandal that precipitated the passage of the 1938 Act. Sulfanilamide, one of the so-called "sulfa drugs," had also come out of the German chemical industry.[218]

The antipyretics illustrated a model of medical patenting that was most similar to that used in other industries. For-profit corporations controlled the new drugs, which had been developed within industrial research laboratories and were marketed under strong patent protection. The drugs were transformative in their effect on patients, dangerous, and expensive. The antipyretics simultaneously offered concrete return on the promises of the new science and realized some of the medical profession's long-standing fears about medical patents. Profits were being made on human suffering, and there was no consideration of medical authority or the public health in any step of the process from drug development to marketing. On the other hand, new drugs now were available, qualitatively different from any available before, as the result of corporate investment in scientific research.

2. MEDICAL RESEARCH AND INSULIN

Germany was the source of most of the early drugs because it had an advanced chemical industry.[219] As the American pharmaceutical manufacturers struggled to reconfigure themselves to succeed in a marketplace involving new, efficacious, patented medicines, they began

216. H.R. Bill No. 11967, 64th Cong., 1st sess. (1916).

217. MCTAVISH, *supra* note 68, at 85 (buying direct); *id.* at 95–96 (proprietary medicine including synthetic anti-pyretic).

218. LESCH, *supra* note 47, at 51–71, 156. Sulfanilamide was the active ingredient of the first sulfa drug, marketed as Protonsil, and was not itself patent-protected in the United States. *Id.* at 156.

219. SKOLNIK & REESE, *supra* note 34, at 11.

to look to university laboratories as a source of products, while also developing in-house research capabilities.[220] Americans lacked the sophisticated chemical experience of the German dye industry but had had success with biological extracts. After Parke-Davis successfully defended its patent for adrenalin isolated from adrenal glands,[221] University of California Professor T. Brailford Robertson patented his pituitary extract, tethelin, convinced that it would prove therapeutically useful.[222] As a university researcher in an era before widespread federal government grants, Robertson was interested in reaping financial gains from his discovery in order to further his research agenda.[223] He convinced the University of California to accept ownership of his patents, and to assume the obligation to commercialize them, in exchange for a promise that any revenues would fund medical research at the University. Robertson and his colleagues at the University published this model of patenting in *Science*,[224] spurring similar models of university-owned patents at the University of Minnesota and elsewhere.[225] Other universities transferred faculty patents to the Research Corporation, an entity created to administer patents for research institutions.[226]

This model of university-controlled medical patents was most prominently and successfully adopted in a university/industry partnership organized by the University of Toronto with the American ethical pharmaceutical manufacturer Eli Lilly.[227] In 1921, a young

220. SWANN, *supra* note 48, at 16–23 (noting that American firms both began to develop in-house capacity and worked with universities before WWI, and detailing industry-university cooperative research in 1920s and 1930s).

221. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 114 (S.D.N.Y. 1911).

222. Growth-Controlling Substance Derived from the Anterior Lobe of the Pituitary Gland and Process for Producing the Same, U.S. Patent No. 1,218,472 (filed Oct. 8, 1915).

223. One large federal source for scientific research at this time was the Department of Agriculture through state agricultural experiment stations. CHARLES E. ROSENBERG, NO OTHER GODS: ON SCIENCE AND AMERICAN SOCIAL THOUGHT 154, 173, 182 (rev. ed. 1997).

224. T. Brailsford Robertson, *The Utilization of Patents for the Promotion of Research*, 46 SCIENCE 371 (1917). A brief discussion of the Robertson plan is provided in Weiner, *supra* note 186, at 51–52. According to Weiner, Robertson's advocacy of patents caused damage to his professional reputation. *Id.* at 50–52.

225. Fishbein, *supra* note 185, at 1315–16 (describing other university-controlled patents after tethelin).

226. Metlay, *supra* note 191, at 569.

227. The history of the discovery and commercialization of insulin is told in MICHAEL BLISS, THE DISCOVERY OF INSULIN (1982), SWANN, *supra* note 48, at 122–49, and Maurice Cassier & Christiane Sinding, *'Patenting in the Public Interest:'*

doctor, Frederick Banting, working with medical student Charles Best in the laboratory of Professor John Macleod, found that a pancreatic extract he had prepared from dogs could be used to reduce the symptoms of diabetes.[228] The researchers originally planned to publish the therapeutic evidence along with the method of production in a medical journal, thus dedicating the extract to the world. This plan foundered when the researchers were unable to solve the problems of reliable mass production of the drug as rapidly as they had hoped. Instead, the University funded a patent application, took assignment of the resulting patent,[229] and entered into an agreement with Eli Lilly to begin commercial production.

The University did not simply turn over the commercialization of insulin to Lilly. It created the Insulin Committee, staffed by university employees, and the Committee set up a licensing program, with the goal of ensuring a safe, reliable, and reasonably priced supply of the drug. Lilly was granted an exclusive license for one year only, and after that initial period, during which time Lilly worked to develop a reliable method of mass production, the Committee licensed other manufacturers.[230] The Committee also set up a quality-control laboratory and tested all drug batches by all licensees for stability and activity.[231]

To American doctors, the introduction of insulin was a great success. The drug produced little miracles all over the country, bringing back children from the brink of death, children whose lives were previously extended only by keeping them on a starvation diet.[232] Insulin, like the antipyretics, was a dangerous drug.[233] Doctors needed to be confident in the strength of the drug as they carefully calibrated treatments for their patients. The successful introduction was understood as the result of an appropriately managed patent portfolio,[234]

Administration of Insulin Patents by the University of Toronto, 24 HIST. & TECH. 153 (2008). The following discussion draws from these sources.

228. MacLeod, Best, and Banting recruited a biochemist, Bertram Collip, to aid the novice scientists, and it was Collip who purified insulin from the extract. BLISS, *supra* note 228, at 11–12, 97–103, 117.

229. U.S. Patent No. 1,469,994 (filed Jan. 12, 1923).

230. While Lilly's formal exclusive period was one year, it was not until almost two years after its initial license agreement, in 1924, that another licensee entered the insulin market. BLISS, *supra* note 228, at 174, 180–81.

231. For details of the licensing program, see Cassier & Sinding, *supra* note 228, at 161–62.

232. *See, e.g.*, BLISS, *supra* note 228, at 43-44, 135–36, 151–52.

233. *Id.* at 157–58 (discussing death from both under-dosage and overdosage).

234. As part of the agreement with Lilly, Lilly assigned to the university patents its employees obtained based on inventions made while developing better methods of manufacturing insulin. Cassier & Sinding, *supra* note 228, at 158–60.

and insulin was discussed at the AMA's 1939 conference on medical patents.[235] The originating scientists and doctors had used the patent to control and modulate the market behavior of manufacturers to support the ethical concerns of organized medicine. Non-exclusive licenses avoided monopoly pricing and enforced quality control over production by licensees ensured reliability. A breakthrough that had originated with a doctor was introduced and administered in medically appropriate ways.

As in Robertson's patent-management model, the University of Toronto received monies to support further medical research. The university had expanded upon his model by insisting on multiple vendors and quality control. Just as Robertson's model had been adopted and modified by Toronto, the role of the Insulin Committee to ensure purity and safety of the resulting drug was adopted and modified by the FDA. The control that the Insulin Committee had maintained through its patent license provisions was considered so crucial that when insulin was coming off patent in 1941, Congress rushed through a bill requiring the FDA to perform this function for all insulin manufactured in the United States, a bill supported by the AMA.[236] Beginning in 1945, the same approach was followed for the new antibiotics—the FDA checked all batches to assure quality.[237]

The insulin experience showed an orderly and successful introduction of a new drug, with high quality control and avoidance of monopoly pricing. By 1941, however, the insulin experience also showed that federal regulation, previously used to force disclosure of trade secrets, could also be used to maintain quality regardless of patent status. This new FDA role was part of a broader switch in food and drug regulation from a focus on providing full information to the consumer to combat the evils of ignorance to a focus on taking some decisions out of the consumer's hands altogether by insisting on a level of safety before a food or drug could be sold.[238] This switch had begun with the 1938 Act which, in reaction to the sulfanilamide scare, had included a requirement that manufacturers needed to submit an application to the FDA before introducing a new drug, including "full

235. F. Lorne Hutchison, *The Administration of Medical Patents for the Public Welfare*, 113 J. AM. MED. ASS'N 330 (1939).

236. Act of Dec. 22, 1941, ch. 613, § 506, 55 Stat. 851, 851–52; TEMIN, *supra* note 5, at 56.

237. TEMIN, *supra* note 5, at 56.

238. With respect to food, there was no pre-market review of any food component until the Food Additives Amendments of 1958, Pub. L. No. 85-929, 72 Stat. 1784, 1784–85. But the food standards promulgated under the 1938 Act were used to control the composition of foods on the market. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, §§ 401–406, 52 Stat. 1040, 1046–49 (1938).

reports of investigations which have been made to show whether or not such drug is safe for use."[239] After sixty days, the application would be deemed approved unless the FDA notified the applicant otherwise, which could be done if the FDA deemed the application to contain insufficient proof of safety.[240] The 1941 amendments to provide for federal quality control of insulin were a further step away from a prevention-of-ignorance model toward a regulatory model in which no knowledge was deemed sufficient to allow consumers to dose themselves, a trend that deepened with the Humphrey-Durham Amendment of 1951 and the Kefauver-Harris Amendments of 1962.[241]

For the American pharmaceutical industry, insulin was also a great success—and a cautionary tale. After the manufacturing problems were solved, Lilly had only a few months of exclusivity before the Committee licensed other manufacturers. Lilly also was pressured to give back to the Committee control over patents it had received to inventions its employees had made while developing the best means of manufacturing insulin.[242] Regardless, Lilly used its head start in the insulin market to maintain a lion's share of the business and to launch its own artificial drug business.[243] It learned that developing drugs in-house, rather than negotiating licenses with doctors with ethical qualms about patents and universities committed to the public interest, would permit exclusivity, and thus monopoly pricing, for the life of a patent. The insulin model of patent control, while lauded by the AMA, could be partially replaced by federal regulation and was unsatisfactory to a key set of players in the drug marketplace, the manufacturers.

3. UNIVERSITY RESEARCH AND VITAMIN D

While insulin was praised as an example of the benefits of medical patents, its success in the 1920s in no way prompted a wholesale embrace of medical patents by organized medicine. Well into the 1930s, the AMA in its official positions, as well as individual physicians, continued to deplore such patents. Another successful university patent portfolio became a lightning rod for medical

239. Federal Food, Drug, and Cosmetic Act § 505(a)-(b)(1).

240. § 505 (c)-(d).

241. The Humphrey-Durham Amendment strengthened the category of prescription medication. Act of Oct. 26, 1951, Pub. L. No. 82-215, 65 Stat. 648, 648–49. The Kefauver-Harris Amendments strengthened the new drug-application process. Drug Amendments Act of 1962, Pub. L. No. 87-781, 76 Stat. 780; *see also* TEMIN, *supra* note 5, at 51–57, 125–26.

242. *See* Cassier & Sinding, *supra* note 228, at 158–60.

243. BLISS, *supra* note 228, at 240–41; SWANN, *supra* note 48, at 149.

suspicions of patents: the Vitamin D patents,[244] obtained by a professor at the University of Wisconsin and granted to the newly created Wisconsin Alumni Research Foundation (WARF) to commercialize for the benefit of the University.[245] Vitamin D supplementation of the diet could help children avoid rickets, a permanently disabling bone disease. Harry Steenbock published his identification of Vitamin D in 1924, delaying publication while he filed a patent application.[246] Steenbock publicly described his patent as a way of protecting the public interest, citing the insulin example.[247] According to historian Rima Apple, Steenbock was motivated by a mixture of public concern, as he wanted to control the development of Vitamin D-enriched products through reputable manufacturers, and a desire to obtain funds to support further research.[248] WARF licensed Vitamin D broadly, allowing manufacturers of many types of products, such as bread, orange juice, and oatmeal, to supplement their products with the nutrient. Five of the "ethical" pharmaceutical manufacturers obtained licenses to manufacture the vitamin: Abbott Laboratories, Mead Johnson, Parke-Davis, Winthrop Chemical Co., and E.R. Squibb.[249] Although in this way, WARF made the benefits of Vitamin D readily available to the American public and avoided monopoly pricing, organized medicine was perturbed, perhaps because Vitamin D was being used as a food additive, lending a new dimension to the old problem of self-dosing. Many doctors were considerably agitated by what they described as the ethical problem of Steenbock and the university profiting from this crucial substance, which should be available to all children. The American Pediatric Association (APA) set up a committee to investigate the many complaints from its members about the licensing program and issued a condemnatory report in 1936.[250] Several years later, the APA

244. U.S. Patent No. 2,057,399 (May 14, 1932); U.S. Patent No. 1,871,136 (Dec. 27, 1926); U.S. Patent No. 1,871,135 (Dec. 27, 1926); and U.S. Patent No. 1,680,818 (June 30, 1924).

245. The Vitamin D patents are discussed in Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Fund*, 80 ISIS 375 (1989), and Metlay, *supra* note 191, at 568–73, from which this discussion draws.

246. Harry Steenbock, *The Induction of Growth Promoting and Calcifying Properties in a Ration by Exposure to Sunlight*, 60 SCIENCE 224, 225 (1924).

247. Apple, *supra* note 246, at 377.

248. *Id.* at 375–76. Steenbock was also motivated by a desire to keep Vitamin D from oleomargarine manufacturers to protect the Wisconsin dairy industry—butter contained Vitamin D, but margarine was deficient without supplementation. *Id.* at 377–78.

249. *Id.* at 386.

250. *Report of the Committee on Clinical Investigation and Scientific Research of the American Academy of Pediatrics, 1935*, 8 J. PEDIATRICS 124 (1936).

turned down a proposed gift of a patent for a way of preserving human milk, refusing to associate itself with patents even to exercise the same type of control as had the Insulin Committee.[251] This suspicion also extended to the scarlet fever antitoxin. After the AMA refused to accept the antitoxin patent, the discoverers managed it themselves through a committee. Despite the fact that the committee licensed four companies to produce the antitoxin to avoid monopoly pricing, the medical community criticized the commercialization of the therapy as not sufficiently within the public interest.[252] While advocating for the ethical use of medical patents in 1937, Fishbein reviewed university-controlled patents and suggested that while such control "has to some extent assured standardization of products," "there are reasons why universities should not hold patents." He argued that the financial rewards of patenting might lead to "a competitive spirit which is likely to destroy entirely the type of cooperation in science that is responsible for much of our current progress."[253] According to Fishbein, state control of patents for the public health was also a dubious idea. Far better, he concluded, that the AMA establish its own non-profit corporation to administer medical patents.[254]

C. The Failure of Patenting in the Public Interest

Despite the success of insulin, then, and despite the endorsement of some academic researchers of patenting in the public interest, the medical profession remained at best ambivalent on the issue of medical patents, particularly when such patents were controlled other than by doctors.[255] This ambivalence proved well founded. The AMA's stated concerns included access to new medications, quality control, pricing, and the further development of medical science through follow-on research.[256] Nearly one hundred years later, critics have identified pharmaceutical patents as a source of problems in all of these areas. The ambivalence of professional medicine, though, was certainly also tied to its long-standing concern that had motivated its condemnation of proprietary medicines: professional status. The AMA's proposal to

251. Kara W. Swanson, *Human Milk as Technology and Technologies of Human Milk: Medical Imaginings in the Early Twentieth-Century United States*, 37 WOMEN'S STUD. Q. 21, 31–32 (2009).

252. Weiner, *supra* note 186, at 53–54.

253. Fishbein, *supra* note 185, at 1317.

254. *Id.* at 1318.

255. Arthur G. Connolly, *Should Medical Inventions Be Patented?*, 86 SCIENCE 383 (1937) (describing differing opinions among doctors about patenting).

256. Fishbein, *supra* note 185, at 1316–18.

control medical patents through a nonprofit corporation was a bid to exercise control of the drug market—control that organized medicine thought it was gaining as it decreased the attraction of the proprietary medicines through the abolition of secrecy. The ethical manufacturers had been a small and relatively docile segment of the drug market, tying their success to medical ethical principles, and courting doctors as their key market, respecting the idea that medicines should be prescribed by professionals, rather than sold to the laity. Through the AMA's proposal, the new patented drugs would be treated like the older formulary drugs—known in composition, use, and recommended strength to all through a centrally controlled information source and manufactured by multiple companies who would compete on the basis of quality and service to their customers, the doctors. The medical profession would control the drug market.

The three vignettes just described show two reasons why this vision of the drug market, briefly advocated by a newly strengthened AMA fresh from a legislative victory, failed to materialize. The first is that the drug patents were often not the property of doctors to assign. Even Banting and Best, the doctors who initiated the discovery of insulin, needed a scientist to help them turn their initial experiments into therapeutic gold. While Banting's sense of medical ethics reportedly initially kept his name off the patent application,[257] his collaborators had no allegiance to medical codes of behavior. Brailsford and Steenbock, as university scientists, may have had their own professional concerns about patents but were more inclined to use university structures than medically controlled organizations to commercialize their innovations. Scientific medicine was separating clinic from laboratory, and large sectors of pharmaceutical development would be occurring without the involvement of doctors. Second, the ethical manufacturers did not see subservience to medicine as their optimal business model. As pharmaceutical companies became corporations, seeking national and international markets, they wanted the same exclusive control over their products which the German chemical companies had shown to be so profitable. With the weakening of the proprietary market, it was the ethical manufacturers, not the medical profession, who would control the contours of the new drugs. Indeed, the ethical manufacturers of the nineteenth century, Eli Lilly, Parke-Davis, Squibb, and others, became the successful U.S.-based pharmaceutical giants of the twentieth century known as "Big Pharma."

257. The more patent-savvy Lilly told the University that in order for the patent to be valid, Banting had to be included as an inventor, according to U.S. patent law. BLISS, *supra* note 228, at 133, 177–78.

The remarkable aspect of the late 1930s in retrospect is not that medical patents became commonplace, unopposed by both the ethical manufacturers and organized medicine, but that for a brief window of time, the medical profession envisioned medical patents allowing a medically controlled drug marketplace. Rather than seeing patents as an unmitigated evil, allowing the privatization of what should be used for the public benefit, the medical profession saw them as a way of increasing its own authority, a counterweight to the profit-oriented firms and the useful, but medically uninformed, federal bureaucrats in the FDA and the patent office. Instead of patents making medical professionals unethical, the control of patents by ethical professionals would make patents, now perceived as necessary aspects of a new, more complicated pharmacopeia, ethical.

Instead, through the federal food and drug regulation and the new science, doctors traded a drug marketplace dominated by secret proprietaries that offered little therapeutic value for a drug marketplace dominated by new corporatized proprietaries that offered medical miracles. Organized medicine had to be content with the control it would increasingly gain as prescription drugs became a legal category. As self-dosing became less common, doctors became the key gatekeepers on the demand side of the burgeoning market in pharmaceuticals. During the course of the twentieth century, doctors gained the ability to control their patient's access to medications, but lost any hope that doctors or medically controlled organizations would exercise control over the supply side. What medications were available for doctors to prescribe would be determined by the drug companies and the FDA.

IV. LESSONS FROM HISTORY

Using the history of science and medicine to rethink the history of early food and drug regulation as intellectual property history, I have emphasized three shifts, all made possible by new ways of seeing and knowing through science. One shift was the transition from federally unregulated markets in food and drugs to the development of federal regulation through the 1906 and 1938 Acts. I have argued that each Act was in part an anti-secrecy act, deliberately constructed to eliminate trade secrets in food products and medicines, at the behest of organized medicine, "ethical" pharmaceutical manufacturers, and agricultural interests.[258] Both the pure-food-and-drug movement and the resulting Acts were anti-intellectual property in their intent.

258. Note that I intend this interpretation to supplement, not supersede, what I have called traditional narratives of the Acts.

I have also traced a related, but distinct, shift in business practices from reliance on trade secrets to reliance on patents within the pharmaceutical industry during this same period. I have argued that while this shift was aided by the new federal legislation, it was caused in large part by the same developments that supported the pure-food-and-drug movement itself—new scientific knowledge and techniques and industrialization.[259]

Finally, I traced a change in attitudes toward medical patents, concentrating particularly on the attitude of professional medicine as evidenced by the AMA, an attitude paralleled by the "ethical" drug manufacturers. From a staunch opposition to both trade secrets and patents—indeed to any form of intellectual property in medicines, including trademarks and copyrights—the AMA moved by the 1930s to a cautious endorsement of medical patents as ethical tools, while the ethical manufacturers moved from spurning anything reminiscent of "patent" medicines to a wholehearted embrace of patent-protected new drugs.

Reconsidering early food and drug law history as intellectual property history is particularly meaningful at our present moment. We find ourselves both continuing to debate the use of patents in the drug market and confronting the enthusiastic embrace of patents by the agricultural industry, the result of the biotechnology revolution that has transformed agricultural science. Like Americans at the turn of the last century, in light of new scientific knowledge and techniques, we are reconsidering what food and drugs are and how to regulate them. It may be time once again to consider food and drug law as intellectual property law.[260] While the present day implications of such a reintegration are beyond the scope of this Article, the lessons of 1938 can provide some guidance for this intersection of concerns.

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259. *See also* CHANDLER, *supra* note 82, at 177 (arguing that the American pharmaceutical industry evolved as part of the second industrial revolution); Jean-Paul Gaudillière, Editorial, *How Pharmaceuticals Became Patentable: The Production and Appropriation of Drugs in the Twentieth Century*, 24 HIST. & TECH. 99, 101–02 (2008).

260. This process is already underway, for example, through analysis of the Hatch-Waxman Act as destroying trade secrets in clinical data and "turning the FDA into a patent enforcement agency." Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 305, 307 (2008); *see also* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007).

A. A Lost Opportunity?

From our position in the first decades of the twenty-first century, we might wish that the AMA had not dropped its formal opposition to medical patents just at the moment when efficacious drugs, the fruits of decades of application of science to medicine, were coming to market. In hindsight, we might contemplate what our drug market would look like today if the United States had adopted the patent reform sought by the AMA in 1849 and reintroduced in 1916, excluding medical products from patentability and allowing only process patents.[261] The collapse of opposition to medical patents in the late 1930s severed the link that had been forged between consumer safety and intellectual property in food and drugs, allowing patent law and food and drug law to develop in relative isolation.[262] Critics have pointed to this isolation as a source of inequities in the present food and drug markets, as a "one-size-fits-all" patent system has been applied to these industries that have particular significance for the public interest.[263] This historical retelling shows that this separation is neither timeless nor inevitable, although it has been consequential.

Before following what-might-have-been too far, however, it is worth setting such wishful thinking in context. There is little evidence that in 1849 or at any time thereafter the AMA had the ability to get

261. H.R. 11967, 64th Cong. (1916); H.R. 755, 30th Cong. (1849). This distinction today is not as clear cut as it seemed to these earlier reformers. Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 33–40 (1991).

262. This isolation can be seen in casebooks. Food and drug law casebooks, such as PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 1629, 1638 (3d ed. 2007), devote only a few pages to patents and patent-law casebooks, such as MARTIN J. ADELMAN, RANDALL R. RADER & JOHN R. THOMAS, CASES AND MATERIALS ON PATENT LAW 979, 983, 988 (3d ed. 2009), similarly devote only a few more pages to recent changes in patent law directly applicable to pharmaceuticals. *See also* FOOD AND DRUG LAW AND REGULATION 900 (David G. Adams et al. eds., 2008); F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 1509 (4th ed. 2008); 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION xiv-xv (3d ed. 2007); ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS xiii (2003).

263. These criticisms have led to some recent changes in patent law specific to the pharmaceutical industry. *See, e.g.*, Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, § 201, 98 Stat. 1585 (to be codified at 35 U.S.C. § 156 (2006)). For a general critique of the "one size fits all" approach, see Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law,* 89 VA. L. REV. 1575, 1674–75 (2003) (arguing both that a unitary system is suboptimal and that courts have developed different rules for different industries), and Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009).

Congress to move on patent reform. Dr. Edwards's proposed bill languished and was not reintroduced in subsequent sessions.[264] In 1900, the more limited suggestion that medical products should be excluded from patentability made no headway with a congressional committee charged with reforming the patent laws.[265] When such a bill was proposed in 1916, despite endorsement by some pharmacists, it again died.[266] Nor had the AMA ever, by its moral disapprobation, stemmed the tide of either medical patents or proprietary medicines. In fact, the market for proprietary medicines grew rapidly during the first decades of the twentieth century.[267] As one observer accurately predicted in 1916, "in spite of the opposition of the medical profession," patenting of medicines "will probably continue."[268] The success of the campaign against trade secrets in medicines only succeeded through a broad coalition and the exploitation of precise political moments to pass each of the 1906 and 1938 Acts. The broad coalition would not have supported anti-patent legislation. Despite the existence of patented artificial foods, such as margarine, the pure-food movement did not contain an anti-patent strain to join with the anti-patent strain among medical-reform advocates. Common ground could be found regarding opposition to secrecy, defined as a lack of consumer information, but not regarding opposition to patents. There was no group to claim that patents in foods were unethical and contrary to the public interest.

Instead of gaining allies against medical patents as the new miracle drugs entered the market under patent protection, the medical profession instead lost a key ally. The "ethical" manufacturers, who had previously used opposition to patents to court favor with doctors, instead worked to transform medical opinion about patents. Francis E. Stewart, doctor turned employee of "ethical" pharmaceutical manufacturers, waged a campaign in the pages of both medical and pharmaceutical journals advocating for patents as ethical tools, along the Robertson-Toronto model.[269] His goal was not only to convince these professional groups to drop their ethical opposition to medical patents, but to convince the pharmaceutical manufacturers which

264. This statement is based on searches in the House of Representative bills and resolutions from the thirtieth to the forty-second Congress (1847–1849 to 1871–1873) for bills containing the terms "patent" or "medicine."

265. S. DOC. NO. 56-20, at 31–32, 35 (1898).

266. H.R. 11967. The Philadelphia branch of the American Pharmaceutical Association endorsed the bill. Stewart, *supra* note 182, at 130.

267. YOUNG, *supra* note 95, at 57 (noting the 60 percent increase in production from 1902 to 1912). Such medicines did not disappear after 1938, either. *Id.* at 390–91.

268. Stewart, *supra* note 182, at 123.

269. Stewart's campaign is discussed in detail in Gabriel, *supra* note 161, at 154–57, 161–65.

employed him that they should and could use patents without becoming unethical manufacturers.[270]

As the tide turned in favor of patents, the AMA not only lacked allies to continue a campaign against medical patents as part of food and drug reform, but also failed to propose a workable alternative to a patent regime. The AMA's earliest and most persistent position was to ban any form of intellectual property in medicines. Any new medicines were to be considered part of the commons, available to all to use and try, allowing doctors to build upon each other's reported results. The doctors carried forward their earliest position even as new types of drugs began to seem possible. If a drug was worth using, the ethical manufacturers could manufacture reliable supplies, just as they had with the previous drugs from the *materia medica*. As shown by the eagerness with which the "ethicals" embraced patented drugs in the twentieth century, this old business model without any intellectual property protection was troublesome. Ethical manufacturers could only sell products that were also sold in exactly the same form by their competition. Even introducing a new drug ethically was nearly impossible, and if a firm could do so, any competitor could establish its own source and quickly enter the market.[271] It was the patented biological extract adrenalin which brought Stewart's first corporate collaborator Parke-Davis a successful new drug and relief from competition for the life of the patent.[272] As Lilly had learned with insulin, and Parke-Davis with adrenalin, exclusive rights to an innovative drug protected by a patent were valuable. Even the few months of exclusivity Lilly received from the University of Toronto allowed the company to take a commanding lead over the competition and finance its transformation into a modern pharmaceutical manufacturer.[273]

Scientific medicine also tended to mean that new cures were coming from the laboratory more than the bedside, which limited the usefulness of the AMA's later proposal—that doctors take out patents but dedicate those patents to the AMA or other nonprofit entities to control in the public interest. Drug development was moving to corporate laboratories. The ethical manufacturers were transforming themselves not only in terms of the drugs they sold, but also in their

270. Stewart began his corporate career by associating with Parke-Davis and later worked for H.K. Mulford & Company and Merck & Company. *Id.* at 161 & n.70.

271. *Id.* at 144–45 (noting that manufacturers had no way of bringing new products into the market while observing ethical norms).

272. *Id.* at 136, 167–68.

273. BLISS, *supra* note 228, at 240; CHANDLER, *supra* note 82, at 194 (noting that Lilly maintained dominance in insulin sales through the 1970s).

corporate structure and approach to drug development.[274] With vertical integration of pharmaceutical manufacturers, the possibility of doctors turning over their new discoveries for patent management by public-spirited medical professionals was vanishing.[275]

There was, perhaps, a lost opportunity to advocate for the more limited proposal—the removal of medical products from the protection of patent laws, allowing patents only to manufacturing processes. Even Stewart, after decades of cheerleading for medical patents as ethical, by 1909 had begun to advocate for this distinction, an adoption of the European model of denying medical product patents.[276] But as pharmaceuticals were becoming an international business, the Europeans themselves were reconsidering their patent laws. The success of the German chemical corporations and their patent portfolios in the drug market provided support for a shift in European social norms and legislative will.[277] In the post-WWII decade, European countries revised their patent laws to *include* medical products.[278] Despite traditional opposition to medical patents in countries like France and England, these countries amended their patent laws to extend protection to medical products.[279] In the atmosphere of a growing international pharmaceutical industry, the AMA would have needed to buck both international as well as national trends to succeed in revising the U.S. patent laws to exclude medical product patents.

The AMA was also in a weaker position with respect to the drug market by 1940 than it had been in 1906. This weakening was partly the result of the growing power of pharmaceutical corporations, as they became modern, vertically integrated business institutions. But it was also a consequence of the creation of the FDA through the 1906 and

274. BLOCHMAN, *supra* note 180, at 353 (noting that after Squibb's death, his sons incorporated his business); CHANDLER, *supra* note 82, at 179; LIEBENAU, *supra* note 37, at 99 (explaining that at the end of WWI, drug companies were "just beginning to take on the form of a mass-production, concentrated industry").

275. To the extent that discoveries, like insulin and Vitamin D, came out of academic labs, the possibility remained for non-corporate control. This solution, as shown by the controversies over Vitamin D, was still unsatisfactory to doctors, who rightly perceived scientists as following a different set of professional norms than the AMA's own Code of Ethics.

276. Gabriel, *supra* note 161, at 164.

277. *See* LESCH, *supra* note 47, at 155–56; Gaudillière, *supra* note 260, at 101, 103.

278. Gaudillière, *supra* note 260, at 101. Countries outside of Europe had also refused medical product patents. The laws on the subject were collected in English translation as of 1900 in S. DOC. NO. 56-20, at 306–12 (1898).

279. Gaudillière, *supra* note 260, at 101–03. Note that many of these countries did preserve a right to grant compulsory licenses to such patents if the patent owner was not practicing the invention within a certain timeframe. *Id.* at 102.

1938 Acts. Before the passage of the 1938 Act, the AMA acted as the sole body certifying safety and efficacy of drugs through its Council on Pharmacy and Chemistry, established in 1905. The Council required manufacturers to submit any products not in the *USP* for analysis, along with full information on ingredients. Though unofficial, the Council had sufficient clout to encourage compliance. Only those drugs that passed muster would be allowed to advertise to doctors in the pages of the *Journal of the American Medical Association*. To supplement the *USP,* the AMA began to publish its own annual volume of approved proprietaries, *New and Non-official Remedies*, which included information on suggested use and dosage.[280] To address proprietary medicines whose manufacturers did not seek Council approval, the AMA established its own Bureau of Investigations with laboratory facilities to expose the secret ingredients in nostrums.[281] The Bureau answered queries from laymen who found government agencies unable to provide them with information and even provided information to municipal and state governments.[282] Further, the AMA did not confine itself to drugs. In 1929, it established a Committee on Foods that issued rules and regulations for the labeling and advertising of foods and awarded complying manufacturers with a "Seal of Acceptance."[283] After 1938, however, these roles were increasingly assumed by the FDA through the nascent regulation of the entry of new drugs and prescription-only medications and the tightened requirements for food labeling.[284]

The 1938 Act was thus not only the high water mark of the pure-food-and-drug movement as anti-intellectual property, but also the high water mark of medical control over the drug market and, to a much lesser extent, the food market. As the rate at which American physicians wrote prescriptions began to skyrocket, and armies of detail men entered doctor's offices to market the new drugs,[285] the medical

280. For a description of the formation of the Council, its rules for analysis and its book, see George H. Simmons, *The Commercial Domination of Therapeutics and the Movement for Reform*, 48 J. AM. MED. ASS'N 1645, 1645–53 (1907). *See also* HARRY M. MARKS, THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900-1990, at 23–26, 32–37 (1997); Burrow, *supra* 106, at 113–15.

281. Fishbein, *supra* note 107, at 50.

282. Cramp, s*upra* note 7, at 51–53 (1933).

283. Raymond Hertwig, *The Work of the Committee on Foods*, 1 L. & CONTEMP. PROBS. 54, 55–60 (1933).

284. The Seal of Acceptance program formally ended in 1955. Harry F. Dowling, *The American Medical Association's Policy on Drugs in Recent Decades*, *in* SAFEGUARDING THE PUBLIC, *supra* note 37, at 123.

285. CHANDLER, *supra* note 82, at 179–80.

profession traded a patron relationship with the "ethicals" and an oppositional relationship with the proprietaries for a co-dependent relationship with Big Pharma. As the stream of new drugs became a torrent, the potential advertising revenues which the AMA was foregoing through the painstaking process of drug evaluation also increased. There were advantages to both the manufacturers and to the AMA if the FDA were to become the sole organization devoted to drug evaluation.[286] The idea that doctors should and could dictate business policies to these corporations began to seem ludicrous to all parties.[287]

While reintegrating the history of food and drug law with the history of intellectual property does not support wistful might-have-beens, it does provide a reminder of the parallels between the pharmaceutical industry and the agricultural industry. In describing the lost opportunity to push the links between food and drug law and intellectual property law further by reconsidering patent policy, I described a pharmaceutical industry that by the 1880s was beginning to realize the advantages of a strong corporate structure and strong patent protection. When the post-WWII boom in the pharmaceutical industry occurred after the successful introduction of sulfa drugs and antibiotics, the industry had over a half-century of movement toward corporatization, industrialization, and patent protection. The agricultural sector has experienced a similar transformation, about a half-century later in time, both in the organization of the industry into large corporations and in a shift from a reliance primarily on trade secrets to a growing enthusiasm for patent-protected products. Within agribusiness, a lost opportunity might be regainable.

B. History Repeating Itself

The food market during the decades of the pure-food-and-drug movement was a market in edibles—fresh and preserved foods moving from farm to city in newly organized and industrialized ways. The artificial foods of the period were new ways of making edibles out of existing crops and livestock—glucose from corn and margarine from hogs, cattle, and plants. Use of patents was confined to processes for preserving food and for making the new artificial foods. Patents covering foods themselves were not the subjects of controversy because they were not even contemplated. The products of the farm—livestock and crops—were part of what was often termed the "common heritage of mankind," a commons, which like the *materia medica*, had been

286. Dowling, *supra* note 285, at 127–29.

287. *But see* MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 35–36 (2004).

expanded by the integration of New and Old World plants and animals, but was not the subject of intellectual property.[288]

I described the ways in which chemistry supported the creation of new foods in the late nineteenth century. In the first decades of the twentieth century, science was not only allowing the creation of new edibles, but also remaking the raw materials from which edibles were made—the seeds from which crops were grown. The new scientific knowledge and techniques during these decades came from Mendelian genetics. Applying genetics, researchers improved the traditional art of plant breeding to develop hybrid strains. Hybrid strains could be bred for more desirable characteristics than their parent strains, but they were not stable—the seeds of crops grown from hybrid seeds would not retain the new characteristics. Farmers needed to go back to a fresh cross of the parent strains each season. This characteristic offered an opportunity for private seed companies to develop commercial property in proprietary seeds—by keeping the parent strains as trade secrets, companies could sell farmers the improved hybrid seeds each season, persuading farmers to give up on their historic practice of collecting seed from their own crops for replanting. During the 1930s, as pure-food-and-drug advocates were pushing what became the 1938 Act, seed companies began to market these trade-secret-protected seeds. Even after the 1938 Act, these trade secrets were outside the regulatory power of the FDA, because they protected products sold to farmers, rather than to the consuming public at retail.[289] In 1938, thinking about food purity and food safety did not encompass thinking about seeds.

This downstream expansion of product lines—from produce to seed—shifted the possibilities for agribusiness. This shift was also supported by the development of fertilizers and insecticides, products of the burgeoning chemical industry that—like the pharmaceutical industry—exploded after WWII.[290] But it was the biotechnology revolution of the 1970s and 1980s that has supported a shift from reliance on trade secrets to patents on seeds and plants, a change of intellectual property practice within agriculture that has raised questions of food safety and economic justice. Just as the pharmaceutical manufacturers were well positioned to exploit the new drugs coming

288. Which is not to say that countries, if not companies, did not try other ways of monopolizing certain crops, such as nutmeg and rubber. AOKI, SEED WARS *supra* note 4, at 11–12. The "common heritage of mankind" characterization has a complex history. *Id.* at 9–10.

289. JACK RALPH KLOPPENBERG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY, 1492-2000, at 93–94, 97–99, 104, 106 (2d ed. 2004).

290. CHANDLER, *supra* note 82, at 46–47, 57, 64.

out of the laboratory after WWII, the agricultural companies[291] were well positioned to take genetically engineered seeds from the laboratory in the 1980s and commercialize patent-protected products.

This transformation in the industry's use of intellectual property was supported not just by new scientific knowledge and techniques, but also by a shift in patent law. While never excluding foods from patentability, the United States had not provided patent protection for plants until 1930 when Congress passed the Plant Patent Act (PPA), providing a particularized type of patent protection for many asexually reproduced species.[292] In 1970, the Plant Variety Protection Act (PVPA) expanded protection to new, useful, and nonobvious sexually reproducing plants.[293] Both the PPA and the PVPA allowed breeders to obtain certificates that were not the legal equivalent of utility patents. The separation of plants from full patent protection came to an end with the *Diamond v. Chakrabarty* decision in 1980.[294] After the Supreme Court determined in that decision that life was no barrier to patentability, the patent office switched its policy and began to issue utility patents to plants.[295] The laboratory offered genetically modified agricultural plants and the patent system offered strong proprietary rights in these modified organisms. Today, many seeds on the market are patent protected. If farmers collect and replant seeds, they can be liable for patent infringement.[296]

Critics argue that such intellectual property protection of seeds and plants is unjust and unethical. It is unjust, it is claimed, in that companies have been allowed to privatize the work of unknown and unnamed farmers by adapting wild-type plants in the laboratory and to tie farmers like serfs to agribusiness by prohibiting seed replanting.[297] It

291. The agricultural companies included both companies who had begun in chemicals and those who began selling seeds, and in some cases, were also pharmaceutical companies. *See, e.g.*, *id.* at 63–68.

292. Act of May 23, 1930, Pub. L. No. 71-245, 46 Stat. 376 (current version at 35 U.S.C. §§ 161–64 (2006)); *see also* AOKI, SEED WARS, *supra* note 4, at 30–34; Daniel J. Kevles, *Patents, Protections, and Privileges: The Establishment of Intellectual Property in Animals and Plants*, 98 ISIS 323, 330 (2007).

293. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. § 2321 et seq. (2006)); *see also* AOKI, SEED WARS, *supra* note 4, at 34–38; Kevles, *supra* note 293, at 330–31.

294. 447 U.S. 303 (1980).

295. *Id.* at 309. While the patent office did not immediately grant utility patents to plants in the wake of *Diamond*, it changed its policy after *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 444 (B.P.A.I. 1985).

296. *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, 903 (Can. S.C.C.); *see also* AOKI, SEED WARS, *supra* note 4, at 49–57.

297. Aoki, *Food Forethought*, *supra* note 4, at 439-40 & n.155; KLOPPENBURG, *supra* note 290, at 274.

is unethical in many of the same ways that the medical profession characterized medical patents as unethical: patents in foods allow the patent owner to control access to life-enhancing substances and to engage in monopoly pricing. The traditional patent policy questions of markets, access, and pricing are linked in contemporary protest movements and litigation with questions of food safety. Is it safe for the American public to drink milk and eat meat from genetically modified organisms? Does the use of genetically modified plants threaten the existence of wild-type plants and animals and thus perhaps threaten the diverse common heritage of mankind that all people depend upon?

Today, then, there is an international agribusiness that depends upon the patenting of seeds, and there is also a growing population of interest groups opposing the practices of this industry, criticizing the reliance on patents and linking intellectual property in food with the public health and safety. Those interest groups—which include consumer advocates, farmers, indigenous peoples, and research scientists concerned with biodiversity[298]—are the possible coalition partners for those advocating for a link between intellectual property in drugs and the public health and safety. They are the allies who did not exist in the 1930s and 1940s and 1950s when the AMA gave up its formal campaign against medical patents. If medical product patents are understood as analogous to patents in agriculturally significant plant genotypes, then there is a basis for once again considering food and drug law as intimately linked with the use of intellectual property protections in food and drug markets. Now, rather than concentrating on trade secrets, the focus needs to be on patent law.

As we consider contemporary agribusiness as, in part, a repeat of our history with pharmaceuticals, the patent system, and federal consumer safety regulation, history offers one more lesson. The linkage between food and drugs that supported the pure-food-and-drug movement as an anti-trade-secret movement was once apparent to legislators in countries around the world as they drafted patent laws. When the AMA pointed to European patent law to support its opposition to medical patents, the medical spokesmen rarely mentioned another category of product often excluded from patentability under those same laws: food. In 1900, Austria, Denmark, Finland, Germany, Hungary, Japan, Luxemburg, Norway, Russia, Sweden, and Tunis (now Tunisia) all excluded medicines *and* food from patentability.[299] At

298. KLOPPENBURG, *supra* note 290, at 292–93.

299. S. DOC. NO. 56-20, at 306–12 (1898). More recently, India adopted this position in its patent law of 1970 (excluding food and medicine from product patents), and then revoked this exclusion in its patent act of 2005. The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India) (amended by Patents (Amendment) Act, 2005, No.

that time, food and medicine, as consumables, were considered outside of the propertization regime of patents and solely the province of food and drug regulations. As we consider how history repeats itself while developing the contours of a new food and drug movement closely informed by questions of intellectual property law, we have the opportunity both to reject failed paths and to borrow productive ideas.

15, Acts of Parliament, 2005. Note that the international regime created by the TRIPs Agreement allows a return to such an approach, permitting member nations to exclude from patentability inventions whose commercial exploitation threatens "*ordre public* or morality," including human life or health. Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81, 94.