The Pure Thoughts of Judge Hand: A Historical Note on the Patenting of Nature

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ABSTRACT

The practice of patenting genetic material is currently under sharp attack. Recent litigation has forced the courts to grapple with the doctrinal basis for patenting genes identical to those found in nature. Faced with conflicting authorities and difficult policy questions, courts have leaned heavily on history to guide—or at least to justify—their decisions.

This essay explores the history in question. It traces the patent law's changing treatment of "products of nature" in an attempt to understand the tangled origins of present-day patentability arguments. Its vehicle for doing so is the case of Parke, Davis & Co. v. H. K. Mulford & Co.*, a century-old decision by Judge Learned Hand, which now stands as a central (and much disputed) precedent for the patenting of DNA sequences.*

The essay combines intellectual genealogy with contextual history. Parke, Davis *arose at a key moment in the sociology of intellectual property, when the American pharmaceutical industry first learned to embrace the power of patents. The essay shows how* Parke, Davis *came to prominence in half-understood form during the biotechnology era, and how the decision's original rationale suddenly seems poised to control the Federal Circuit's latest thinking on gene patentability.*

I. INTRODUCTION

Today, it is possible in the United States to patent the genetic material of a living organism, as long as it is isolated from the host animal, plant, virus, or bacterium. This information sometimes startles lay audiences. Surely, they ask, patent law protects only new inventions? How can a DNA sequence already present in an organism—present, perhaps, in *me*—be the subject of a new or future patent?

It's not a bad question. Any student of patent law could tell you that the Patent Act requires "novelty,"[1] a criterion that one might expect

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[1] 35 U.S.C. §102.

to exclude (for example) genes carried by generations of our own ancestors. Most could also tell you that the subject-matter provisions of the Act have been broadly construed to cover all human-made inventions: the Supreme Court's guiding opinion on biotechnology patents, *Diamond v. Chakrabarty*,[2] famously contemplates protection for "anything under the sun that is made by man."[3] Artificially-modified life forms, such as those produced by genetic engineering, fit that description easily. Patents for DNA sequences identical to those found in nature, on the other hand, might seem to stretch the definition of what is human-made.

Patent law follows the same intuition, up to a point. A long line of cases rejects patents for natural artifacts. Courts and the Patent Office have invalidated claims for extracted plant material,[4] for purified forms of existing metals,[5] and for new combinations of bacteria,[6] to name some of the leading examples. Though based on a clutch of different rationales, these decisions are thought to form a loosely aggregated "product-of-nature" doctrine excluding naturally occurring articles from patentability.[7]

Fortunately for would-be gene patentees, the product-of-nature prohibition comes with a significant loophole. Products that have been "isolated" from their natural state and "purified," or rendered free from associated materials, have been recognized as patentable in an almost equally long line of cases. The governing logic of this exception—that such products do not exist in their isolated form in nature, and have useful properties not found in the natural form of the material[8]—has enabled patent law to embrace biological products ranging from hormones and vitamins in the early twentieth century to DNA sequences in the early twenty-first.

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[2] 447 U.S. 303 (1980).

[3] *Id* at 309. The phrase appears in the legislative history of the 1952 Patent Act. In its full context this quotation is far less permissive than usually supposed: "A person may have 'invented' a machine or a manufacture, which may include anything under the sun made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled." H. R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952).

[4] *Ex parte Latimer*, 1889 Dec. Com. Pat. 123 (1889).

[5] *Gen. Elec. Co. v. De Forest Radio Co*., 28 F.2d 641, 642 (3d Cir. 1928); *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931) ("Marden I"); *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931) ("Marden II").

[6] *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127, S.Ct. 440, 92 L.Ed. 588 (1948).

[7] *See, e.g.* 1-1 Chisum on Patents § 1.02 [7], "Product of Nature--Biological Subject Matter."

[8] U.S. Patent and Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.")

Thousands of gene patents have issued under the isolated-and-purified rubric in the past twenty years.[9] Those patents, and the theory underlying them, are now under heavy attack. In the 2010 case of *Association for Molecular Pathology et al. v. U.S. Patent & Trademark Office et al.*[10]—widely known as the *Myriad* case after one of the co-defendants, Myriad Genetics—a group of physicians and researchers represented by the American Civil Liberties Union challenged patent claims relating to two human genes: Breast Cancer Susceptibility Genes 1 and 2 (BCRA1 and BRCA2). Judge Robert Sweet of the U.S. District Court for the Southern District of New York jolted the biotechnology world by holding the claims invalid. Taking clear aim at the isolation-and-purification doctrine, the court cited legal commentators and "scientists in the fields of molecular biology and genomics [who] have considered this practice a 'lawyer's trick' that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result."[11]

This decision of a U.S. District Court would ordinarily have little chance of hauling down the doctrinal framework of modern gene patenting. The odds quickly changed, however, thanks to an unexpected development on appeal: the United States government entered the fray as *amicus curiae* to argue that isolated genomic DNA is not patentable after all.[12] The U.S. government's litigating positions typically exert remarkable influence on courts' patent policy decisions.[13] *Association for*

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[9] *See, e.g., Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, Fed. Cir., Jul. 29, 2011 ("It is estimated that the PTO has issued 2,645 patents claiming 'isolated DNA' over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome" [internal citations omitted]). The source for most such estimates is a now-dated quantitative study of gene patents, Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE, 239, 239 (2005). The notion that patents "cover" twenty percent of the human genome is disputed: *see* Christopher M. Holman, "Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth that Twenty Percent of the Human Genome is Patented," draft paper available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1894715.

[10] *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[11] Id. at 185, quoting John M. Conley & Roberte Markowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 305 (2003).

[12] Brief of the United States as Amicus Curiae in Support of Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, Fed. Cir. No. 2010-1406 (October 29, 2010); Alison Frankel, "Amicus Shocker: DOJ Opposes PTO Policy, Says Genes Not Patentable," THE AMERICAN LAWYER, November 4, 2010.

[13] John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 Geo. Wash. L. Rev. 518 (2010); Colleen V. Chien, *Patent Amicus Briefs: What the Courts' Friends Can Teach Us About the Patent System*, forthcoming in U. C. I. L. Rev. (2011), online at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1608111 (noting that between 1989 and 2009 every single amicus brief authored by the United States in a Supreme Court patent case except one predicted the case outcome). One sub-plot to

Molecular Pathology thus became a contest of usually-irresistible forces in patent law: on one side the weight of the federal government's position, and on the other the settled expectations of the inventing community and the enormous vested interests of the patent-holding biotechnology sector.

Sure enough, the Federal Circuit's ruling in the case, delivered in July, 2011, was a split decision.[14] Two members of the three-judge panel voted to uphold the BRCA patent claims relating to isolated DNA sequences, although under different theories.[15] The third panel member found isolated genetic material unpatentable.[16] Petitions for certiorari in *Association for Molecular Pathology* were filed in mid-December. Given the splintered opinions, the high stakes of the dispute, and the probability that the U.S. Government will maintain its position, further review remains likely. Whatever the outcome, it is clear that a substantial part of the ongoing legal battle will be waged over the history of patent law and practice. Arguments at trial in *Association for Molecular Pathology* suggested as much, with the parties respectively laying claim to "almost 100 years of jurisprudence" supporting patentability[17] and "long-established Supreme Court precedent," going back to the nineteenth century, to the contrary.[18]

The historical range of this dispute is not mere window-dressing, but a typical feature of high-level patent contests more generally. Patent jurisprudence has emerged over time as a field with strong judge-made elements, drawing the courts back again and again to nineteenth-century authorities.[19] Among patent doctrines, the question of patentable subject-matter is perhaps the area of the law most shaped by non-statutory common-law edicts.[20] And within this area, both the product-of-nature

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watch is that attorneys from the U.S. Patent and Trademark Office pointedly did not appear on the United States' amicus brief.

[14] *Ass'n for Molecular Pathology*, 653 F.3d 1329 (Fed. Cir., 2011).

[15] *Ass'n for Molecular Pathology*, slip opinion of Lourie, J., at 35-48; *id.*, slip opinion of Moore, J., at 13-19.

[16] *Ass'n for Molecular Pathology*, slip opinion of Bryson, J., *passim*.

[17] Myriad Defendants' Memorandum in Reply to Plaintiffs' Opposition to Myriad Defendants' Motion for Summary Judgment, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, S.D.N.Y, No. 09 Civ. 4515 (January 29, 2010), 23 (Hereafter "Defendants' January 29 Memorandum").

[18] Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, S.D.N.Y, No. 09 Civ. 4515 (August 26, 2009), 19 (Hereafter "Plaintiffs' Memorandum").

[19] Among recent Supreme Court cases alone, *see, e.g.*, *Bilski v. Kappos*, 130 S.Ct. 3218, 3221 (2010) (citing *Le Roy v. Tatham*¸ 55 U.S. 156 (1852)); *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 618 (citing *Bloomer v. McQuewan*, 56 U.S. 539 (1853)); *KSR v. Teleflex*, 550 U.S. 398, 405 (2007) (citing *Hotcbkiss v Greenwood*, 52 U.S. 248 (1850)); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 723 (2002) (citing *Winans v. Denmead*, 56 U.S. 330 (1853)).

[20] For example, the definition of patentable subject-matter in §101 of the Patent Act says nothing about the "well established" exceptions for "laws of nature, physical phenomena, and abstract ideas." *Bilski v. Kappos*, 130 S.Ct. 3218, 3226 (2010); 35 U.S.C. §101. *See*

rule and its isolation-and-purification exception have the distinction of being well-established traditions with relatively vague legal foundations.

This historical indeterminacy is a potential problem. Not because knowing the "right" interpretation of ancient cases would produce the "proper" outcome in the gene-patent cases. Given the scale of the interests at stake, it would be a stretch to assume that judges will let fidelity to precedent, rather than policy concerns, dictate their decisions. Instead, the historical cases will likely be used to supply an account of why the chosen outcome is conceptually coherent and continuous with earlier practice. If the reasoning of those opinions is twisted or reframed in the process—as recent patentable-subject-matter decisions suggests it might be—then the result will be less clarity rather than more. The essay that follows is thus a somewhat hopeful attempt to clarify the history at issue.

My vehicle for doing so is one of the foundational cases in the gene patenting debate, and the best emblem of historical confusion: *Parke, Davis & Co. v. H. K. Mulford Co.*[21] In this case, decided in 1911, the celebrated Judge Learned Hand upheld a patent for adrenalin derived from animal glands. For the defenders of gene patents, Learned Hand's decision represents the foundation of the isolation-and-purification exception, and thus the beginning of the long judicial tradition underpinning modern patents for genetic material. For opponents, Hand's opinion represents a fateful divergence from the true bar on patenting products of nature. Whatever one's position, *Parke, Davis v. Mulford* "is now a standard citation for the theory permitting patents on DNA sequences,"[22] having been cited in nearly two hundred law-review and periodical articles in the last twenty years.[23] For a trial court ruling to carry such influence is a fascinating anomaly, and one that requires some explanation.

That is, however, only the beginning of *Parke, Davis*'s complications as a source of authority. One strand of this essay will trace the changing meanings of Judge Hand's decision, beginning with an assessment of what it meant at the time. Hand's opinion was not the great doctrinal innovation that its reputation suggests. Nor was it the broad endorsement of natural-product patents that it has frequently been taken to be: *Parke, Davis* did not support patentability for merely isolated and

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also John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009). On patent law as a "hybrid" field combining statutory and common-law requirements, with the Patent Act as a "common law enabling statute," *see e.g.* Craig Nard, *Legal Forms and the Common Law of Patents*, 90 B. U. L. REV. 51, 53 (2010); Rochelle C. Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L. J. 787, 803 (2008).

[21] *Parke, Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).

[22] ROBERT MERGES AND JOHN F. DUFFY, PATENT LAW: CASES AND MATERIALS, 4TH EDITION, 112 (2007).

[23] Westlaw, search of citing references, last undertaken May 15th, 2011.

purified substances. Instead, Hand's reasoning required an additional factor of commercial or therapeutic value that for a while, fell out of the modern understanding of the case. With the Federal Circuit's opinions in *Association for Molecular Pathology*, though, that aspect of the *Parke, Davis* decision has newly returned to the forefront—and in fact, has been retrospectively presented as the crux of natural-product patenting.

The other strand of the essay follows a different theme: a story about the sociology of intellectual property. *Parke, Davis* gives a glimpse into a very unfamiliar world, in which the U.S. pharmaceutical industry was reluctant to employ patents as a business tool. That changed, and changed rapidly, right around the time of the adrenalin case. At the very least, the story of *Parke, Davis* is a window into the process of change; at most, the adrenalin patent battle itself may have helped to transform the intellectual property culture of the pharmaceutical and life-science industries.

The approach of the essay is a mixture of intellectual genealogy and contextual history. Part II relates the story of *Parke, Davis* and reconstructs its legal, scientific, and commercial setting. Part III considers the correctness of Hand's decision in light of the law at the time, and then proceeds to explore the subsequent uses of the opinion. Finally, Part IV concludes with some observations on the current and future implications of *Parke, Davis* in the gene patenting debate.

II. THE STORY OF *PARKE, DAVIS & CO. V. H.K. MULFORD CO.*

Parke, Davis & Co. v. H. K. Mulford Co. did not take place in a world of legal abstraction. Far from it: the circumstances that produced the litigation were freighted with contemporary concerns over science, medicine, and political economy. Understanding the result—and hence the reasoning—of the *Parke, Davis* decision requires some attention to each of these contexts.

A. Background: Patents, Science, and Industry

Start with the two parties, Parke, Davis & Co. and the H. K. Mulford Company. Both were part of an American pharmaceutical industry that began to emerge in the late nineteenth century. Parke, Davis was formed in Detroit in the 1860s as a partnership between Hervey Coke Parke and George S. Davis, absorbing the business of the pharmacist and manufacturing chemist Samuel Duffield. Incorporating in 1875, it was soon joined in the drug manufacturing business by a group of firms that included Eli Lilly, G.D. Searle, and Abbott Laboratories.[24] The H. K. Mulford Company was a later arrival: a prosperous Philadelphia pharmacy

[24] DAVID F. NOBLE, AMERICA BY DESIGN: SCIENCE, TECHNOLOGY, AND THE RISE OF CORPORATE CAPITALISM (1977), 15.

that turned to manufacturing in 1891, licensed newly-developed tablet-making machinery, and quickly joined the front rank of pharmaceutical companies.[25]

These firms collectively occupied a distinctive space in the market. For most of the nineteenth century, the supply of medicines in America had been dominated by purveyors of "nostrums" or "patent medicines" (a misnomer, since most were unpatented and protected, if at all, via trademarks and trade secrets). The makers of popular patent medicines were, first and foremost, pioneers of marketing; superbly successful at promoting branded products whose all-purpose active ingredients were often alcohol or opium.[26] Eventually the gap between advertised promise and therapeutic reality became a public and political liability. Proprietary medicines faced a growing chorus of criticism from physicians and pharmacists on grounds of their quackery and blatant commercialism. By the turn of the twentieth century, muckraking exposés of the "Great American Fraud" had made patent medicines a byword for abuse and a regulatory target of the Progressive Era's pure food and drug movement.[27]

In this climate, the new generation of pharmaceutical companies worked hard to distinguish themselves from the peddlers of nostrums. They adopted the label of "ethical" manufacturers, aligning themselves with the assertive respectability of the medical profession.[28] They also undertook to become "scientific" enterprises. Firms hired medical men and constructed laboratories for quality control and research. Parke, Davis & Co., one of the pioneers of this practice, formed close relationships with the University of Michigan. H. K. Mulford did the same with the Philadelphia College of Pharmacy.[29] During the late 1890s, the two firms competed for the title of "most advanced scientifically."[30]

Medical discoveries, meanwhile, began to move the drug trade beyond the panaceas of yesteryear. The basic stock-in-trade of the "ethical" companies during the 1890s still consisted of botanicals and simple chemical compounds, together forming the *materia medica*, or storehouse of known remedies.[31] New scientific products were emerging,

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[25] JONATHAN LIEBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY (1987), 57-58.

[26] JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION (1961); T. J. JACKSON LEARS, FABLES OF ABUNDANCE: A CULTURAL HISTORY OF ADVERTISING IN AMERICA (1995) 142-53.

[27] SAMUEL HOPKINS ADAMS, THE GREAT AMERICAN FRAUD (1906); YOUNG, *supra* note 23, chapters 13 & 14; Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WISC. L. REV. 329, 340-55 (2011).

[28] LIEBENAU, *supra* note 22, at 4.

[29] *Id.* at 8-9.

[30] *Id.* at 34.

[31] *See, e.g.* PARKE, DAVIS & CO., DESCRIPTIVE CATALOGUE OF THE LABORATORY PRODUCTS OF PARKE, DAVIS & COMPANY (1894). The catalog indicated, for example, the following prescriptions for gout: "Aconite, Belladonna, Colchicum, Dulcamara,

however. First, research in industrial chemistry began to spin off medical applications. German chemists working with the materials of the coal-tar dye industry developed the earliest modern pharmaceutical products, starting with a series of antipyretics (fever reducers) that appeared in the 1880s, and continuing in the 1890s with acetylsalicylic acid (then trademarked, and now known generically, as aspirin).[32] British and American experimenters focused more on biological research and on the extraction and purification of natural substances.[33] Research into the glandular products that would soon be known as hormones met with promising results in the mid 1890s.[34] Also in the 1890s, diphtheria antitoxin became the first widely-deployed biological therapeutic to emerge from scientific medicine, demonstrating the possibilities of the bacteriological understanding of disease. As the subject of an immediate distribution campaign by U.S. public health authorities, this antitoxin also became the first real bulk-manufacturing mainstay of the "ethical" drug companies, Parke, Davis and Mulford included.[35]

The place of patents in these new pharmaceutical fields was a delicate question. The "ethical" companies' priorities lay in cozying up to the medical profession and holding the old patent-medicine trade at arm's length. Thanks in part to the disrepute of the nostrum business and in part to the non-commercial pretensions of the medical profession, the organized medical establishment had a longstanding policy against doctors patenting any drug, instrument, or surgical technique. Individual physicians did patent, but the profession's official disapproval of patents was repeatedly reaffirmed.[36]

Pharmaceutical companies took varying approaches in response. H. K. Mulford went furthest to accommodate the anti-patent norm. In 1900 the firm adopted a "Statement of the Relations of the H. K. Mulford Company to the Medical and Pharmaceutical Professions," whose first pledge was to forswear "monopoly obtained either by secret formulas or processes or product patents."[37] Parke, Davis took a somewhat different tack. Although it declined to seek patents on any of its products during the 1880s, Parke, Davis became increasingly comfortable with carrying

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Guaiac, Lappa, Lithium citrate, Phytotecca root, Potassium iodide, Strychnine, Sulphides."

[32] GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCES INDUSTRIES, PAST, PRESENT, AND FUTURE (2nd edn, 2009), 15-17, 83-84.

[33] DUTFIELD, *supra* note 29, at 85-86; Swanson, *supra* note 24, at 377. Some of this emphasis may have been the result of trends noted above: expertise in purification was one of the side-effects of both the pure food and drug movement and of pharmaceutical companies' "ethical" investments in stringent quality control.

[34] DUTFIELD, *supra* note 29, at 104-8. Hormones were given that name by the English scientist Ernest Henry Starling in 1905.

[35] LIEBENAU, *supra* note 22, at 48-51.

[36] Swanson, *supra* note 24, at 366-68.

[37] LIEBENAU, *supra* note 22, at 64.

patented products in the 1890s.[38] Even so, patenting and patent enforcement were not central aspects of the company's strategy. Like other American pharmaceutical firms, Parke, Davis only gradually embraced patents as a business tool.[39]

One group did patent drugs in the United States: the Germans. Having emerged from the industrial chemical sector, German synthetic drug makers began with a predisposition to adopt the chemical industry's intensive and sophisticated patenting behavior, both at home and abroad. German chemical companies in the late nineteenth century delighted in the use of American and British patent laws to leverage their formidable lead in laboratory-based research and development. Without product patents in their home country (which allowed only process patents for chemicals), German firms like BASF, Hoechst, AGFA, and Bayer sought them in large numbers in the U.S. and U.K. By the turn of the century, German firms were receiving more than 75% of all British and American dye patents, and succeeded in gaining legal control over large swathes of those countries' dyestuffs and chemicals markets as a result.[40]

On a far smaller scale (simply because the market was far smaller), the same pattern was echoed in pharmaceuticals. Bayer held the American patent on Phenacetin, the most prominent of the antipyretics, as well as owning the Aspirin patent. Both were enforced against all comers through Bayer's U.S. agent, the Farbenfabriken of Elberfeld Company.[41] Another particularly controversial grant was Emil von Behring's 1898 U.S. patent for diphtheria antitoxin. With American pharmaceutical companies already manufacturing the antitoxin in large quantities, the appearance of this patent briefly threw the industry into panic, but Hoechst, the owner, perhaps wisely decided not to enforce it.[42]

German strategic patenting lent the whole question of drug patents in the United States a protectionist edge. Some of the most direct public-

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[38] J. 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. OF MED. & ALLIED SCI. 135, 160 (2009).

[39] LIEBENAU, *supra* note 22, at 8. Liebenau takes the view that patent-based strategies did not become central to the U.S. pharmaceutical industry until after the First World War.

[40] Jonathan Liebenau, "Patents and the Chemical Industry: Tools of Business Strategy," in LIEBENAU (ED.), THE CHALLENGE OF NEW TECHNOLOGY: INNOVATION IN BRITISH BUSINESS SINCE 1850 (1988); JOHANN PETER MURMANN, KNOWLEDGE AND COMPETITIVE ADVANTAGE: THE COEVOLUTION OF FIRMS, TECHNOLOGY, AND NATIONAL INSTITUTIONS (2003), 40.

[41] DUTFIELD, *supra* note 29, at 16-18.

[42] *See, e.g. The Antitoxin Patent of Behring*, 12 AMERICAN MEDICO-SURGICAL BULLETIN 847 (1898) ("Professor Behring will reap only a harvest of shame and not the harvest of American dollars that he expected . . . Messrs. Parke, Davis & Co. and the H. K. Mulford Company have agreed to fight the patent to the bitter end and to protect all users of their serums from any interference on the part of the holders of the patent"); *see also* DEREK LINTON, EMIL VON BEHRING: INFECTIOUS DISEASE, IMMUNOLOGY, SERUM THERAPY, 239 (2005).

policy discussion of pharmaceutical patenting in the early twentieth century took place during debates over congressional bills that aimed to curtail foreign dominance. The Mann Bill of 1904 and the Paige and Edmonds Bills of 1915 proposed to eliminate drug product patents and to require that any drug-related patent be worked in the United States within two years of issue.[43] The druggists' association that prepared the Mann bill clearly had Bayer's Phenacetin patent in mind: sponsoring Congressman James Mann waved a large package of the drug during hearings, complaining that what sold for $1 per ounce in the United States cost only $1 per pound across the Canadian border and in the rest of the world.[44]

In retrospect, the history of medicine, business, and patents during this period is both like and unlike the story of the gene patenting era. Among the greatest differences is the character of the American pharmaceutical industry, which in the late nineteenth and early twentieth centuries was quite unlike the IP-oriented economic juggernaut of the post World War II years. Early pharmaceutical companies may have been at the forefront of "scientific industry," but in terms of scale and scope they were somewhere between wholesale pharmacists and a minor branch of the fine-chemicals sector.[45] On the other hand, some of the tensions surrounding patenting in the human sciences look very familiar. Questions were raised about the propriety of patenting medical compounds in the nineteenth century just as they were raised about patenting life in the twentieth, and for similar ethical and utilitarian reasons. In both periods, some of the institutions central to biomedical research were—at least initially—deeply ambivalent about patenting: the "ethical" pharmaceutical companies in the nineteenth century; bodies like the National Institutes of Health and (for a time) the universities in the twentieth. Perhaps fatefully, these hesitant patentees operated in close proximity to actors with aggressive patenting cultures, be they German chemical firms in the earlier period or American and multinational pharmaceutical companies later. If these parallels suggest anything, it is this: that cultures of intellectual property are not a given in the life sciences, but once awakened, they prove hard to stop.

B. Patent Law: Chemicals, Drugs, and Products of Nature

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[43] Hearings before the Committee on Patents of the House of Representatives on H.R. 13679, Introduced by Mr. Mann, Amending the Statutes Relating to Patents on Drugs, Medicines, and Medical Compounds, 1904 ("1904 Hearings"); Swanson, *supra* note 24, at 370.

[44] 1904 Hearings, *supra* note 40, at 27-28. With admirable candor, Representative Mann stated that "[t]he bill which I introduced . . . is not a bill which was prepared by me, and I had nothing to do with its preparation. It was prepared, as I understand, by an attorney, if not the attorney, of the National Retail Druggists' Association." *Id.* at 26.

[45] Noble, *supra* note 21, at 3-6, 15.

Two currents run through the legal background to *Parke, Davis v. H. K. Mulford*. The product-of-nature doctrine is now by far the better known, though at the time of *Parke, Davis* it was fairly obscure. The other theme of the case lies in the evolving jurisprudence of chemical and drug patenting.

1. A "Product of Nature" Bar?

Descriptions of the prohibition against patenting products of nature are often hazy about its beginnings. Part of the problem is that some of the standard references are not actually product-of-nature decisions at all. For example, the doctrine is sometimes traced to the 1874 case of *American Wood-Paper Co. v. Fibre Disintegrating Co*.[46] This is an unfortunate instance of miscasting. In *American Wood-Paper*, the U.S. Supreme Court considered a claim for chemically-treated wood pulp (essentially, cellulose extracted from wood), and rejected the patent for want of novelty. Because the case featured natural materials and was extensively cited in later decisions about extraction and purification, commentators have periodically leapt to the conclusion that it turned on the unpatentability of naturally-existing cellulose.[47] In fact, the Court found that cellulose from vegetable fiber had been "produced and used in the manufacture of paper long before" the date of the patent.[48] Invalidity resulted from the human prior art, rather than from anything to do with the natural existence of cellulose in wood.[49]

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[46] 90 U.S. (23 Wall.) 566 (1874). *See, e.g.* Linda J. Demaine and Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303, 332 (2002) ("The Supreme Court's first close examination of the patentability of 'purified' natural products was the 1874 case American Wood-Paper Co. v. Fibre Disintegrating Co.")

[47] *See, e.g. Ass'n for Molecular Pathology*, 702 F. Supp. 2d, at 223 ("Courts have also specifically held that "purification" of a natural compound, without more, is insufficient to render a product of nature patentable. In *The American Wood-Paper Co. v. The Fibre Disintegrating Co*., the Supreme Court held that refined cellulose, consisting of purified pulp derived from wood and vegetable, was unpatentable because it was 'an extract obtained by the decomposition or disintegration of material substance.'" [internal citations omitted]); Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 976 (2011) ("Historically, purified natural products were not always patentable").

[48] *American Wood-Paper Co.*, 90 U.S. at 594.

[49] Note, however, that the Circuit Court opinion below included language that came close to a product-of-nature argument. ("I should feel bound to say that it appears impossible to consider that to be a new material, patentable as a new product, which is simply a substance long well-known to exist in wood and other substances, left in a state 'nearly pure,' and consequently fit for the manufacture of paper on being bleached by the removal from it of the intercellulose with which it is found to be combined in wood." *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 1 F. Cas. 728, 729 (Wheeler, J., C.C.E.D.N.Y. 1868)). The Supreme Court nowhere endorsed this position.

The next canonical decision in the supposed product-of-nature line is *Cochrane v. Badische Anilin & Soda Fabrik* (BASF).[50] Here, the notion of an operative product-of-nature doctrine would initially seem to be on more solid ground. The German chemical firm BASF held an extremely valuable U.S. patent for synthetic alizarine, a red dye produced from coal tar. Alizarine had long been obtained in natural form from the root of the madder plant. Accordingly, defendants at the Supreme Court argued, *inter alia*, "that alizarine is a natural product, having a well-known definite constitution; that it is not a composition of matter, within the meaning of the statute, but has been well known in the arts, from time immemorial, for the purpose of dyeing."[51] This was a novelty defense that overlapped with a product-of-nature argument: artificial alizarine was not new because it was chemically identical to the natural dye in the prior art.

On closer examination, however, the Court's disposition of the case took scant notice of the product-of-nature argument. Justice Blatchford's opinion focused on the defendant's non-infringement, based on a construction that limited the BASF patent to the product of the specific process described in its specification.[52] Only after doing so did Blatchford briefly note "another view of the case," in which the synthetic alizarine was an "old article . . . [which] could not be patented, even though it was a product made artificially for the first time . . . Calling it artificial alizarine did not make it a new composition of matter, and patentable as such."[53] At best a secondary holding of the opinion, this language moved to the cusp of *obiter dicta* with Blatchford's subsequent statement that "[i]t is so clear that the defendants are not shown to have infringed that we have not deemed it necessary to consider other questions any further."[54] Later product-of-nature cases repeatedly cited *Cochrane v. BASF*, just as they did *American Wood-Paper*, but not because the patented substance had appeared in nature. Instead, the significance of the case lay in its indication that a known product derived from a new source or process lacked sufficient novelty to be patented in its own right.

The first true product-of-nature decision came in 1889, and did not issue from a court at all, but as an opinion of the Commissioner of Patents. *Ex parte Latimer* concerned a fiber extracted from pine needles, the patentee claiming "as a new article of manufacture the fiber herein described, consisting of the cellular tissues of the *Pinus australis* eliminated in full lengths from the . . . pine needles and subdivided into long, pliant filaments."[55] The invention was a relatively high-profile one: cotton farmers across the South were then embroiled in a "Great Jute

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[50] Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884).
[51] *Id.* at 297.
[52] *Id.* at 309-311.
[53] *Id.* at 311.
[54] *Id.* at 312.
[55] *Ex parte Latimer*, 1889 Dec. Com. Pat. at 123.

Boycott" against the Jute Trust, which controlled the bagging of cotton; Latimer's pine fiber offered an alternative to jute and was thus, as the opinion noted, "unquestionably very valuable."[56] Commissioner Benton J. Hall (an Iowa lawyer-politician with no obvious stake in the Jute Boycott) hinted at the commercial and political sensitivities of the invention when he declared his "anxiety, if possible, to secure to the applicant a patent."[57] Even so, the Commissioner affirmed the patent examiner's decision to reject the application, holding that the fiber was "a natural product and can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by . . . some new method of reaping can be patented as wheat cut by such a process."[58]

Ex parte Latimer cited no direct authority for its conclusion.[59] Instead, Commissioner Hall pointed to the lack of human alteration of the extracted fiber, which had not been "in any manner affected or produced by the process, or . . . in any wise been affected, changed, or altered."[60] Plant fiber in general was "a well known material, the knowledge of which is almost co-extensive with the human family"; at most, Latimer had discovered only the particular properties of the *Pinus australis*.[61] And applicant's "mere ascertaining of the character or quality of trees that grow in the forest . . . is not a patentable invention . . . any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found."[62] Behind these observations lay the logical conclusion of allowing the patent: "it would be possible for an element or a principle to be secured by patent," and that ultimately "patents might be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible."[63] For good measure, the Commissioner warned darkly that if Latimer could secure a patent for the fiber of *Pinus australis*, "an alleged inventor in Germany [might] acquire a patent which would give him the exclusive use of the *Pinus sylvestris*."[64]

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[56] *Id.* at 127. *See also* "To Fight The Jute Trust," *New York Times*, April 4, 1889; "The Story Of An Industry. How Pine Bagging Came To Be Brought Into Use," *New York Times*, May 26, 1889; MICHAEL SCHWARTZ, RADICAL PROTEST AND SOCIAL STRUCTURE: THE SOUTHERN FARMERS' ALLIANCE AND COTTON TENANCY, 1880-1890 (1988), 235-46.
[57] *Ex parte Latimer*, 1889 Dec. Com. Pat. at 127.
[58] *Id.*
[59] The Commissioner did mention—without endorsing—the cases cited by the Patent Examiner below: *Cochrane v. BASF* (cited for the point that a substance identical to that in the prior art cannot be patented); *American Wood-Paper* (paper pulps made from different vegetable substances deemed not patentable as separate products); and two other wood-pulp cases. *Id.* at 124.
[60] *Id.* at 125.
[61] *Id.*
[62] *Id.*
[63] *Id.* at 125-26.
[64] *Id.* at 126.

There is no doubt that *Ex parte Latimer* is a completely on-point product-of-nature decision: a direct and powerful statement against the patentability of merely isolated or extracted natural materials. Before using the case as historical authority, though, it is worth asking whether it carried the weight that has subsequently been imputed to it. First, although *Latimer* is sometimes cited as an "example" of how the Patent Office denied patents for purified products of nature, it is not clear that the decision was representative.[65] A thorough survey of patent records is beyond the scope of this paper, but patents certainly did issue for extracted natural products that were unaltered or barely altered from their natural state. Four months before the *Latimer* decision, Arthur Bailey of Newton, Mass. received a patent for clam juice that was merely extracted from the clam, filtered, and boiled.[66] Patents subsequently issued for such products as resin extracted from vanilla beans and the isolated perfume of the orris root.[67] In 1898, the Scottish chemist Edward Stanford received a patent for the extracted active constituents of the sheep thyroid gland "in the form and condition and in the proportions in which they were originally present in the said gland."[68] The reasoning of *Latimer* was either disregarded in such instances or was so easily avoided (by "changes" like heating or filtering) as to be trivial.[69]

There is also very little to suggest that *Latimer* was known beyond the Patent Office. The decision did not appear in the major patent treatises

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[65] *C.f.* Demaine & Fellmeth, *supra* note 43, at 333 ("The Commissioner of Patents accordingly denied patent applications for purified products of nature throughout the nineteenth century. In the 1889 decision in Ex parte Latimer, for example . . .). *See also* Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 323 (1995) ("Initially, lower courts also viewed natural products as unpatentable. In Ex parte Latimer, for instance . . .").

[66] U.S. Patent 395,199, "Clam Extract," issued to Arthur Bailey, December 25, 1888.

[67] U.S. Patent 931,805, "Oleoresin of Vanilla," issued to Edward J. Sheehan, August 24, 1909 (describing invention that differed from prior art vanilla extracts "principally in that it is an oleoresinous extract from the vanilla bean, and contains not alone the vanillin principle but a large part of the group of resins constituent in the bean"); U.S. Patent 559, 638, "Process for Making Ketone from Orris-Root," issued to Johann Carl Wilhelm Ferdinand Tiemann, May 5, 1896 (Claiming "[a]s a new product a fragrant ketone of the composition $C_{13}H_{20}O$, (natural violet ketone of orris-root)" and noting that "While extract of orris-root has heretofore been used, the aromatic principle has to my knowledge never been separated and used in its isolated condition").

[68] U.S. Patent 616,501, "Product from Thyroid Glands and Process for Making Same," issued to Edward C. C. Stanford, December 27, 1898.

[69] Conversely, it is all but impossible to tell how often *Latimer* was used to reject patents. Based on an electronic text search, the decision seems never to have been cited by name in the *Decisions of the Commissioner of Patents* during the next half-century. *See* Hein Online, Decisions of the Commissioner of Patents and of the United States Courts in Patent and Trademark Cases, 1869-1944. If *Latimer* had been an oft-used authority at the time—even a clear, unchallenged authority—one would expect to see it cited at least occasionally on appeal to the Commissioner, if only to distinguish the case.

of the day, although these discussed patentable subject-matter at length.[70] No reported court decisions cited *Latimer* in the nineteenth century or the first two decades of the twentieth. This absence might be explained by a lack of litigation arising on the relevant point of law,[71] though *Parke, Davis v. Mulford*, for one, casts some doubt on that proposition. The 1920s, 1930s, and 1940s, however, saw a number of decisions that rejected patents on explicit product-of-nature grounds, and they do not mention *Latimer* either.[72]

The point of this discussion is not to prove that products of nature were generally deemed patentable: only a more systematic search of issued patents could properly establish that. On the other hand, it seems as though the now-vaunted decision in *Ex Parte Latimer* may have had limited purchase at the time. At any rate, the state of both law and Patent Office practice before *Parke, Davis v. Mulford* supplied relatively little guidance for the courts.

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[70] *See, e.g.* WILLIAM CALLYHAN ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS (3 vols., 1890); ALBERT H. WALKER, TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA (3rd ed. 1895, 4th ed. 1904). As far as I can tell, *Latimer* was cited almost exclusively in digests of Patent Office opinions and rules: *see, e.g.* GEORGE H. KNIGHT, PATENT OFFICE MANUAL: INCLUDING THE LAW AND PRACTICE OF CASES IN THE UNITED STATES PATENT OFFICE AND THE COURTS HOLDING A REVISORY RELATION THERETO, 402 (1894); AMOS W. HART, DIGEST OF DECISIONS OF LAW AND PRACTICE IN THE PATENT OFFICE AND THE UNITED STATES AND STATE COURTS IN PATENTS, TRADE-MARKS, COPYRIGHTS, AND LABELS, 1886-1898, 244 (1898) (where it was the only case listed under heading "Products of Nature"). The exception is *Latimer*'s appearance in a digest of chemical patent opinions produced in the early twentieth century, where the holding was summarized vaguely and unhelpfully as "Product is not patentable unless novel." EDWARD THOMAS, A DIGEST OF PROCESS AND COMPOSITION AND ALLIED DECISIONS IN PATENT CASES, 23 (1908).

[71] As a rough indicator, the first reported patent decision to use the phrase "product of nature" occurred in 1919, and applied the phrase somewhat oddly to machine-made glass. *See Consolidated Window Glass Co. v. Window Glass Mach. Co.*, 261 F. 362, 370 (3rd Cir. 1919). This could be evidence that the *Latimer* doctrine was widely accepted such that no patentee tried to enforce a patent drawn to a product of nature. However, it may also indicate that the product-of-nature category was in practice extremely narrow, and that any substance subjected to the slightest human alteration or processing was treated as a regular invention and assessed by standard criteria of novelty, etc.

[72] *See, e.g. Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928); *In re Marden*, 47 F.2d 957, 957 (C.C.P.A. 1931); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

2. Chemical Inventions: Novelty through Greater Utility

By contrast, patents for chemical products had generated extensive discussion in the courts. *Parke, Davis v. Mulford* followed on the heels of a set of chemical and drug patent decisions that loomed far larger in the law than the marginal product-of-nature doctrine.

For example, one recurring issue in the law of chemical product patents was—and still is—the relationship between process and product.[73] Chemical inventors frequently sought to claim both a new process and the product that resulted from the process. Many of these end products were synthetic copies based on natural-product precursors, natural active principles in newly purified form, or closely-related variants or analogs of prior-art chemical products.[74] Courts were thus periodically pressed to decide whether an old product produced in a new way could be the subject of a patent. More than anything else, *American Wood-Paper* and *Cochrane v. BASF* addressed themselves to this new-process-old-product issue.[75] *Cochrane* was widely believed to have settled the issue against the patentability of old products obtained from new sources or by new means.[76]

Questions remained about how differentiated a product had to be from the prior art in order to achieve patentability. Purification posed one such challenge: what to do about an invention that produced a previously-known substance at a hitherto-unprecedented degree of purity? Dicta in *American Wood-Paper* suggested that "a slight difference in the degree of purity of an article" would not support a product patent.[77] At least one court had consequently concluded that a product merely containing fewer impurities than appeared in the prior art would not be patentable.[78]

As the pace of chemical innovation quickened, however, the courts proved willing to reward the practical gains that came with new, purer substances. Judges began to hold that greater utility provided grounds for a patent, even if the only difference between the new product and the prior

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[73] *See, e.g. Abbott Labs. v. Sandoz, Inc*., 566 F.3d 1282 (Fed. Cir. en banc, 2009) (resolving a long-running intra-circuit split on the scope of claims that define a product in terms of the process used to create it). *Cochrane v. BASF* was the central authority in dispute in the case: *see id*. at 1311 (Newman, J., dissenting).

[74] Dutfield, *supra* note 29, at 107.

[75] In both cases, the Court framed the issue in terms of an old product derived from a new source. *American Wood-Paper*, 90 U.S. at 593-94 ("the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture . . . Thus, if one should discover a mode or contrive a process by which prussic acid could be obtained from a subject in which it is not now known to exist, he might have a patent for his process, but not for prussic acid"); *Cochrane*, 111 U.S. at 311.

[76] Robinson, *supra* note 67, at vol. I, pp. 274-75; THOMAS, DIGEST, *supra* note 67. at iv.

[77] *American Wood-Paper*, 90 U.S. at 594.

[78] *Blumenthal v. Burrell*, 53 F. 105, 107 (2d. Cir. 1892).

art lay in the degree of purity.[79] In *Blumenthal v. Burell* (1892), the Second Circuit found that an extract of the enzyme chymosin, "separated from pepsin, and uncombined with foreign substances . . . was not merely an improved, but an absolutely new, article, having its own distinctive nature."[80] In *Union Carbide Co. v. American Carbide Co.* (1910), the same court upheld a patent for calcium carbide in a new crystalline form, stating that "patentable novelty in a case like the present may be founded upon superior efficiency."[81] The opinion in *Union Carbide* explicitly referenced the utility of the invention as a consideration in its novelty decision: "To hold an important discovery which has given to the world a commercially new product—a product the high utility of which must be conceded—not entitled to protection for want of novelty, would, as it seems to us, be applying the patent statute to defeat its fundamental purposes."[82] As a later treatise on chemical patenting explained, "It is the utility which is controlling, and a composition having new utility, not previously obtainable by those skilled in the art is patentable even if it differs from another only in degree."[83]

This reasoning reached its most prominent expression in 1910, in the biggest pharmaceutical case to date. *Kuehmsted v. Farbenfabriken of Elberfeld Co.*[84] tested Bayer's patent for aspirin (acetylsalicylic acid), "the best selling medicine on the market," with sales of two million ounces per year.[85] As with phenacetin, Bayer's earlier mainstay, the popularity of the patented drug led to large-scale smuggling and imitation, which the German company countered through litigation.[86] Chicago pharmaceutical wholesaler Edward A. Kuehmsted was one of the leading aspirin bootleggers and was chosen as the target of Bayer's test case.[87]

At trial, Kuehmsted argued that the aspirin invented and patented by Bayer's scientist Felix Hoffman was not new. Salicylic acid had been known for many years as a remedy for rheumatism and fever, but caused adverse side effects such as stomach pain. In the search for an improved treatment, Kuehmsted pointed out, acetylsalicylic acid had been produced in impure form, notably in experiments by the German chemist Johann Kraut. Both the U.S. Circuit Court in Chicago and the Court of Appeals for the Seventh Circuit accepted that Kraut's impure substance had been

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[79] EDWARD THOMAS, CHEMICAL PATENTS AND ALLIED PATENT PROBLEMS, 32 (1917) ("A product may be patentable because of its utility even if merely purer or in more useful form than the prior art shows").
[80] *Blumenthal*, 53 F. at 107.
[81] *Union Carbide Co. v. American Carbide Co.*, 181 F. 104, 106 (2d. Cir. 1910).
[82] *Id.* at 108.
[83] THOMAS, CHEMICAL PATENTS, *supra* note 76, at 34.
[84] 179 F. 701 (7th Cir. 1910).
[85] *Id.* at 702.
[86] JANICE RAE MCTAVISH, PAIN AND PROFITS: THE HISTORY OF THE HEADACHE AND ITS REMEDIES IN AMERICA (2004), 112-33; DIARMUID JEFFREYS, ASPIRIN: THE REMARKABLE STORY OF A WONDER DRUG (2005), 91-92.
[87] JEFFREYS, 91.

identified by the same chemical formula as aspirin, but noted that those impurities had rendered the compound "comparatively useless."[88] In his pure acetylsalicylic acid, Hoffman, on the other hand, had "produced a medicine indisputably beneficial to mankind—something new in a useful art, such as our patent policy was intended to promote."[89] As a result, even though "the two bodies [were] analytically the same," "Hoffmann's recrystallized product [was] therapeutically different."[90] The greater utility of the purified form made it a patentable invention.

The rule of patentability-through-efficacy is unfamiliar to patent law today. As a conceptual matter, it entailed collapsing together a number of inquiries that would now be separate: those of novelty (difference from the prior art), utility (existence of some known use as a threshold qualification for patentability),[91] and nonobviousness (use of "objective indicia" such as commercial success in demonstrating the presence of patentable invention).[92] In practice, the approach was a fairly straightforward policy of ensuring reward to the inventors of valuable inventions. This too is not technically the modern practice—patent law at least formally does not consider the merit of the invention in resolving patentability—but was of a piece with other patent doctrines at the time. Foremost of these was the notion of the "pioneer patent," which afforded broader scope to breakthrough inventions.[93] As one legal authority put it, "[t]he first inquiry is whether the patent is a primary one; that is, for a pioneer invention… In the case of a primary patent greater liberality is shown in construing its claims so as to protect it against equivalents."[94]

Early twentieth-century patent law thus included (at least) two possible approaches to the status of a purified natural product. On the one hand, *Ex parte Latimer* afforded a potential bar to substances entirely unmodified from their natural state. On the other, chemical patent decisions gave great weight to any hint of a modification from the prior art, if it provided the crucial step to the creation of a valuable new product.

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[88] *Farbenfabriken of Elberfeld Co. v. Kuehmsted*, 171 F. 887, 890 (C.C.N.D.IL. 1909)
[89] *Kuehmsted*, 179 F. at 705.
[90] *Id*. at 704.
[91] Chemical patent law thus operated for much of the twentieth century with two different analyses of utility. A 1960 Note described the situation thus: "Utility, then, has two meanings in the law of chemical patents: (1) the narrow technical sense of that minimum utility necessary to meet the constitutional and statutory standard for a compound whose existence was not predictable; and (2) that utility which appears to be used interchangeably with such terms as "unexpected results" or "unobvious beneficial properties" and which thereby becomes also a standard of patentable novelty. Note, *Utility as a Factor in Chemical Patentability*, 108 U. PA. L. REV. 1037, 1044-45 (1960).
[92] *See, e.g.* Michael S. Greenfield, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1068-69 (1992).
[93] *See* Brian J. Love, *Interring the Pioneer Patent Doctrine*, N.C. L. REV. (forthcoming), available online at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1804546.
[94] William K. Townsend, "Patents," in TWO CENTURIES' GROWTH OF AMERICAN LAW, 1701-1901, ED. MEMBERS OF THE FACULTY OF THE YALE LAW SCHOOl (1901), 406.

Of these two strains, only the latter had a visible effect on the business of medical technology. For those working to develop medicines from the emerging corpus of biological knowledge, there was thus ample reason to hope for the protection of the law.

C. The Adrenalin Patents

Research into adrenalin grew out of discoveries in physiology and pharmacology. In 1894, the physician George Oliver and physiologist Edward Schäfer, of University College London, reported the blood-pressure-raising effects obtained from an extract of animal suprarenal (adrenal) glands. The therapeutic possibilities of this discovery for surgical use and for the adrenal deficiency known as Addison's disease spurred an immediate search for the active substance—or what chemists then called the active "principle."[95] In 1897, the Johns Hopkins pharmacologist John J. Abel (regarded as the "Father of Pharmacology" in the United States) produced a crystalline substance which he believed to be the blood-pressure-raising constituent of Oliver and Schäfer's extract, albeit in impure form. Abel called his discovery "epinephrin," and went on to publish descriptions and a chemical formula.[96] Meanwhile the Austrian chemist Otto von Fürth isolated a similar compound, which he called "suprarenin."[97] A form of Fürth's glandular extract went to market, proving useful to medical practitioners. Unfortunately, the impurities in the extracted matter made it prone to rapid decomposition and dangerous to administer by injection.[98] Further purification promised major therapeutic and commercial gains. The firm of Parke, Davis & Co. was soon in the hunt: Thomas Aldrich, a former colleague of Abel's at Hopkins, had joined the company's Biological Laboratory and set to work on further isolating the active principle.[99] He would, however, not be the one to make the breakthrough.

That role fell instead to Jokichi Takamine. Takamine was a Japanese chemist, educated in Tokyo and Glasgow, who had lived and worked in the United States since 1890. His background lay in agricultural chemistry and fertilizers, and he had briefly served as an official in the new Japanese patent office, but he had spent the bulk of his years in America developing a malt diastase, an enzyme product mainly

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[95] E. M. Tansey, *What's in a Name? Henry Dale and Adrenaline, 1906*, 39 MEDICAL HISTORY 459, 464-65 (1995).

[96] JOHN PARASCANDOLA, THE DEVELOPMENT OF AMERICAN PHARMACOLOGY: JOHN J. ABEL AND THE SHAPING OF A DISCIPLINE (1992), 57-58.

[97] Tansey, *supra* note 92, at 465.

[98] Jokichi Takamine, *Adrenalin the Active Principle of the Suprarenal Glands and Its Mode of Preparation*, 73 AM. J. PHARM. 523, 523 (1901); *Parke, Davis*, 189 F. at 106; WALTER SNEADER, DRUG DISCOVERY: A HISTORY (2005), 155 (marketing of Fürth's suprarenin by Hoechst).

[99] Horace W. Davenport, *Epinephrin(e)* 25 PHYSIOLOGIST 76, 78 (1982).

used in distilling.[100] Between 1889 and 1896, Takamine took out a series of U.S. patents involving the fungal preparation known in Japan as *koji*, which he grew on moist bran to produce his diastase extract. Takamine failed to win over the distilling industry, but he did succeed in attracting a different client: Parke, Davis & Co., which undertook to market his diastase as a remedy for indigestion.[101] "Taka-Diastase" proved successful, and Parke, Davis maintained its association with Takamine. At the company's instigation and with a supply of fresh animal glands, Takamine began research on the active principle of the adrenal gland.[102] Some time before the Fall of 1900, Takamine succeeded in extracting the pure active principle from Abel's compound by the relatively simple technique of precipitating it with ammonia.[103] With this step, Takamine had succeeded in isolating the first ostensibly pure hormone.[104] He called it "Adrenalin."

Takamine filed for a patent on his invention in November 1900. It is quite likely that this was his own initiative, rather than that of Parke, Davis. Takamine had considerable experience and success with patenting. Parke, Davis, while it had marketed patented products like Taka-Diastase, had at that point never purchased a patent prior to issue.[105] It would not acquire Takamine's adrenalin patents until May of 1904, nearly a year after they were granted. Even though the norms against pharmaceutical patenting had begun to soften before 1900, it is not self-evident that Parke, Davis would have sought to patent the new substance for itself.

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[100] David L. Cowen, "Takamine, Jokichi," in JOHN A. GARRATY AND MARK C. CARNES (ED.), 21 AMERICAN NATIONAL BIOGRAPHY 265–66 (1999); Davenport, *supra* note 96, at 78-79.

[101] Davenport, *supra* note 96, at 79.

[102] Deposition of Frank G. Ryan, President of Parke, Davis & Co., Trial Record, 309-10. Ryan's testimony describes Takamine as "a chemist in the employ" of the company, but I have not been able to corroborate this. *See also* Davenport, *supra* note 96, at 79 (noting that E. M. Houghton, Director of Parke, Davis' Research Laboratory, performed physiological tests for Takamine).

[103] Davenport, *supra* note 96, at 79.

[104] Takamine's extract later turned out to contain two hormones, adrenaline and noradrenaline (or epinephrine and norepinephrine). PARASCANDOLA, supra note 93, at 58.

[105] Patents could be assigned by the inventor to another firm or individual at the time of issue; when this happened, it usually reflected either an employment or financing relationship between the inventor and the assignee. Naomi Lamoreaux and Kenneth Sokoloff, "Inventors, Firms, and the Market for Technology: U.S. Manufacturing in the Late Nineteenth and Early Twentieth Centuries," in LEARNING BY DOING IN FIRMS, MARKETS, AND COUNTRIES, ED. NAOMI LAMOREAUX, DANIEL M. G. RAFF, AND PETER TEMIN (1999), 19-60. My conclusion that Parke, Davis had received no assignments-on-issue before 1901 is based on a search of Google Patents: given the imperfections of text searching in this database, the conclusion should be regarded as tentative. The first patent that I can find assigned to Parke, Davis & Co. on issue is E. M. Houghton's U.S. Patent 715,661, "Vaccinating Tool," filed March 5, 1901, issued December 9, 1902.

In any case, it quickly became clear that the adrenalin patent application would face legal obstacles. Takamine's original application, drafted by the New York patent solicitors Knight Bros., included seven process claims and two product claims. One product claim was for "the product Adrenalin, consisting of the active principle of the Suprarenal Glands, in a white, solid, crystalline form"; the other was for a salt of the active principle.[106] Patent Office examiner James Littlewood, an experienced member of the Office's Division of Chemistry, immediately rejected the claims as "drawn to a product of nature, merely isolated by applicant, and hence . . . not drawn to such patentable subject matter as required by statute."[107] Littlewood cited *Ex parte Latimer* and *Cochrane v. BASF* as authority without further elaboration. Knight Bros. may have been surprised by the rejection: their next communication did not rebut the examiner at length, but merely protested "that the compounds named here do not exist in a state of nature in the form defined by these claims . . . The product as it exists in nature is certainly not a white, solid, crystalline body."[108] The examiner reaffirmed the rejection, adding a citation to the *Wood-Paper Patent Case*.[109]

In an amended application nearly a year later, Takamine's lawyers now made a fuller version of their change-of-form argument. Taking *Latimer* as the "official interpretation" of the product-of-nature doctrine, they argued that the decision had turned on the fact that the fiber was in no way "'affected, changed, or altered' from its natural condition."[110] That claim had "covered no more than a natural object, unchanged from native condition except that it was withdrawn or abstracted from its natural setting, as a pebble might be picked out of a mud bank," and thus had been properly rejected for lack of novelty.[111] By contrast, Takamine's active principle had never existed as a white, crystalline substance, and its "complete transformation" rendered it "therefore new."[112] The argument failed: Littlewood responded that the transformation was really no more than a separation; the active principle did not exist "free from impurities in

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[106] Jokichi Takamine, "Glandular Extractive Products," application of November 5, 1900. Reproduced in "Record" (hereafter "Trial Record,"), *Parke, Davis & Co. v. H. K. Mulford Co.*, Case #4363, U.S. Court of Appeals for the Second Circuit, 1911, box 1684, RG276, National Archives and Records Administration New York Region, New York City.

[107] Communication from Examiner, December 7, 1900, Trial Record at 878. The second claim, Littlewood argued, disclosed nothing more about the salt than that it shared the properties of the natural principle; "The natural principle not being patentable, neither is this." *Id.*

[108] Jokichi Takamine, Amendment, October 22, 1901, Trial Record at 883.

[109] Communication from Examiner, November 7, 1901, Trial Record at 884.

[110] Jokichi Takamine, Amendment September 25, 1902, citing *Ex Parte Latimer*, Trial Record at 887.

[111] *Id.* at 888.

[112] *Id.* at 889.

nature; neither did Latimer's fibre, but it did exist and therefore is not patentable."[113]

Thus foiled, Takamine changed course. In a new patent application containing sixteen product claims,[114] Takamine reframed both what he claimed and how he claimed it. Instead of claiming "the active principle" of the gland, the claims now embraced "a substance having the herein-described characteristics and reactions of the suprarenal glands."[115] Accompanying remarks explained that the sixteen claims were framed "to distinguish and identify" the substance: some did so by specifying an appearance, others described a melting-point, solubility, or reaction with a known chemical. This was hall-of-mirrors claiming, seeking to reflect the compound from every conceivable angle.

Most importantly, Takamine's attorneys now stressed the relationship between purity and function. They pointed out that the Commissioner in *Ex parte Latimer* had explicitly allowed for patentability if the inventor added "some new quality or function" which a natural substance "does not possess in its natural condition."[116] "Applicant is the first to produce a substance which is stable and does not deteriorate nor decompose on keeping," they noted.[117] Accordingly, key claims specified the product "in a stable and concentrated form, and practically free from inert constituents."[118] An attached memorandum distinguishing the *American Wood-Paper*, *Cochrane*, and *Latimer* cases abandoned Takamine's old emphasis on physical form, and focused on "definite properties and characteristics which [the glandular substance] does not possess in nature," particularly "permanence and stability."[119] These also happened to be precisely the characteristics that made Takamine's Adrenalin a significant medical advance.

That was enough. After some minor amendments, the application was approved and granted in June 1903 as U.S. Patent 730,176.[120] Takamine received a patent (no. 730,175) for his process claims on the

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[113] Communication from Examiner, October 17, 1902, Trial Record at 890.

[114] With the product claims removed, the process claims of Takamine's first application were approved and issued as U.S. Patent 730,175, "Process of Obtaining Products from Suprarenal Glands," granted to Jokichi Takamine, June 2, 1903.

[115] Jokichi Takamine, Application of January 14, 1903, Amendment of March 14, 1903, Trial Record at 842-44. Takamine explained his sudden redefinition of his claimed substance by saying that further experiments had suggested the presence of other active principles in the gland, which he did not seek to claim. Takamine, Amendment of April 30, 1903, Trial Record at 851-52.

[116] *Id.* at 847, quoting *Ex parte Latimer*.

[117] Jokichi Takamine, Amendment of March 14, 1903, Trial Record at 845.

[118] *Id.* at 842-44.

[119] *Id.* at 846.

[120] U.S. Patent 730,176, "Glandular Extractive Product," granted to Jokichi Takamine, June 2, 1903.

same day, and a further patent for a salt of the active principle (no. 753,177) a few months later.[121]

D. Adrenalin on Trial

Parke, Davis & Co. began to market Adrenalin almost immediately after Takamine's discovery. The hormone's initial application was as a drug to stop bleeding in minor surgical procedures, making it particularly attractive to eye surgeons, dentists, and ear, nose, and throat specialists.[122] "As cocaine is to painless surgery," the company boasted, "so Adrenalin [is] to bloodless surgery."[123] Sold in both powdered and solution forms, Adrenalin quickly supplanted the dried adrenal glands and gland extracts already available. Parke, Davis sold more than $30,000 worth of Adrenalin products in 1901, more than $100,000 in 1902, and almost $200,000 in 1904. It was the firm's greatest success to date.[124] In 1905, however, sales fell back to $130,000, and thereafter grew only slowly.[125] Competition had entered the market. A variety of companies offered rival products, including Armour & Co. (Suprarenalin), Eli Lilly (Sanguestine), H.K. Mulford (Adrin), and others.[126] That same year, Parke, Davis commenced litigation under its patents.

Two suits were filed against the H. K. Mulford Company in the U.S. Circuit Court for the Southern District of New York, both alleging patent infringement by Mulford's branded product Adrin.[127] Parke, Davis chose to sue under its two product patents (one for the pure isolated Adrenalin, one for a salt of the hormone), but not under its associated process patent. The reason, the company later explained, was that the process patent would not reach imported goods, and thus "to sustain the process without the product patent would be to discriminate against American manufacturers in favor of importers of foreign manufacture," which the company "did not wish to do if it can be avoided by

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[121] U.S. Patent 730,175, "Process of Obtaining Products from Suprarenal Glands," granted to Jokichi Takamine, June 2, 1903; U.S. Patent 753,177, "Glandular Extractive Compound," granted to Jokichi Takamine, February 23, 1904.

[122] *See, e.g.*, Sydney Stephenson, "Ocular Therapeutics," 131 MEDICAL PRESS AND CIRCULAR 183, 183-84 (1905).

[123] Brief of Parke, Davis & Co., *Parke, Davis & Co. v. H. K. Mulford Co.*¸ Case #4363, U.S. Court of Appeals for the Second Circuit, 1911, box 1684, RG276, National Archives and Records Administration New York Region, New York City (hereafter "Brief of Parke, Davis"), 13.

[124] Deposition of Frank G. Ryan, President of Parke, Davis & Co., Trial Record, 310-12.

[125] *Id.* at 310.

[126] "The Suprarenal War," 16 PRACTICAL DRUGGIST AND REVIEW OF REVIEWS, 328 (August 1904).

[127] *Parke, Davis & Co. v. H. K. Mulford Co.*¸ cases S-9232 and S-9233, U.S. Circuit Court for the Southern District of New York. *See* Equity Docket, C.C.S.D.N.Y., Volume S, RG21, National Archives and Records Administration New York Region, New York City ("Equity Docket").

enforcement of the product patents."[128] Given that H. K. Mulford continued to trumpet its high-minded stance against drug product patents in general,[129] it may have seemed wise for Parke, Davis to invoke the looming specter of German competition as a justification for wielding them.

The parties spent fully five years gathering evidence and testimony in the case. Counsel for both sides were major figures of the patent bar. Livingston Gifford, the New York patent lawyer who had represented Bayer in the *Kuehmsted* case, appeared for Parke, Davis & Co. Howson & Howson, Philadelphia's leading patent law firm, appeared for Mulford. The bulky record of proceedings was devoted mostly to the depositions of a small number of expert witnesses, principally Charles F. Chandler, an eminent New York professor of chemistry and pharmacy, who testified for Parke, Davis; and Samuel P. Sadtler, a longtime professor of organic and industrial chemistry at the University of Pennsylvania, who testified for Mulford.[130] Both scientists were repeat players in such cases: Chandler had appeared for the patentees in *Kuehmsted* and in other cases involving BASF and Bayer; Sadtler had been the principal witness for the defense in at least one of the phenacetin cases.[131] Sadtler's testimony in *Parke, Davis*, which took up most of the record, was largely based on experiments he performed at Mulford's request. This material did much to give the case its unremitting density of technical detail, as well as, in retrospect, the decision's uneasy ruminations about partisan science in the courtroom.

Eventually the record in *Parke, Davis v. Mulford* crashed onto the desk of a judge: one Billings Learned Hand. Learned Hand, as they say, needs no introduction, other than perhaps the widely-repeated assessment that he was "one of the four greatest judges of the first half of the twentieth century."[132] In years to come, he would be known, among other things, as a great authority in patent law.[133] In early 1911, though, he was a relative novice on the bench, newly escaped from a disappointingly tepid career as a Wall Street lawyer.[134] By becoming a federal judge of the Southern District of New York, Hand had certainly put himself on the front line of

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[128] Brief of Parke, Davis, *supra* note 120, at 3.
[129] See above, note 34 and accompanying text.
[130] Depositions of Chandler and Sadtler, Trial Record at 17, 404.
[131] *See, e.g. Kuehmsted*, 179 F. at 703; *Badische Anilin & Soda Fabrik v. Higgin*, 2 F. Cas. 348, 350 (C.C.S.D.N.Y. 1878); *Maurer v. Dickerson*, 113 F. 870, 872-73 (3d Cir. 1902).
[132] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d, at n. 46, quoting *Remarks of the Honorable John M. Walker, Jr. Upon Receiving the Learned Hand Medal for Excellence in Federal Jurisprudence*, 76 ST. JOHN'S L.REV. 595, 596 (2002)
[133] *See, e.g.* Stephen H. Philbin, *Judge Learned Hand and the Law of Patents and Copyrights*, 60 HARV. L. REV. 394 (1947); GERALD GUNTHER, LEARNED HAND: THE MAN AND THE JUDGE, 256, 258-59, 313 (1994).
[134] On Hand's career at the bar, see GUNTHER, *supra* note 137.

American patent law. The Circuit Court[135] of the S.D.N.Y. was the most important patent venue in the country, and suits of this kind made up a large part of its docket. In 1910 alone, nearly three hundred patent suits were filed in the district, roughly twenty percent of all civil suits commenced there.[136] Judge Hand decided sixteen patent cases before he filed his opinion in *Parke, Davis*¸ having been on the court for all of twenty-four months.[137] Fortunately Hand was well equipped for this type of work, being possessed of a powerful grasp of detail. He also manifested a healthy, longstanding skepticism about the value of adversarial expert testimony, having written an article ten years earlier on "Historical and Practical Considerations Regarding Expert Testimony."[138]

Arguments in the trial record did not focus on the product-of-nature issue. If the parties' contentions had a single major theme, it concerned the novelty of Takamine's products in the face of various alleged anticipations by other scientists. John J. Abel and Otto von Fürth were the principal candidates to have pre-empted Takamine in their own experiments with the suprarenal extract. Each had created compounds containing the active principle in combination with other substances. Judge Hand decided, however, that these materials could not anticipate Takamine's '176 patent for a purified extract of the adrenal gland. Hand reasoned that Takamine's claims were drawn only to the base of the active principle, and were "especially designed to exclude a salt," which was claimed in the later '177 patent. Because "all of four alleged anticipating products never existed except in the form of a salt," none could anticipate.[139]

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[135] Not to be confused with the U.S. Circuit Courts of Appeals, the U.S. Circuit Courts were a holdover from the pre-1891 days when justices of the Supreme Court had ridden circuit. For the most part, they functioned as trial courts operating with the territory and the bench of the corresponding District Court. The circuit courts were finally folded into the District Courts in 1911. While they existed, the Circuit Courts had exclusive jurisdiction over patent cases. *See* ERWIN C. SURRENCY, HISTORY OF THE FEDERAL COURTS, 48 (2002).

[136] This percentage is highly approximate. 296 patent suits were filed in the calendar year 1910. *See* Docket Books and Case files of the Circuit Court for the Southern District of New York, RG21, National Archives New York Region, New York. 1,457 civil suits were commenced in the District and Circuit Courts of the district in the fiscal year 1910. *See* U.S. Department of Justice, Annual Report of the Attorney General of the United States for the Year Ended June 30, 1910, 151 (1910).

[137] A full list of Hand's district court decisions is given in the Finding Aid to the Learned Hand Papers at the Harvard Law School Library, available online at http://oasis.lib.harvard.edu/oasis/deliver/~law00059.

[138] *See* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40 (1901).

[139] *Parke, Davis*, 189 F. at 102. Hand did find that Abel's compound anticipated a claim of Takamine's '177 patent, and that "Takamine cannot claim to have been the first to discover a stable and pure salt having the physiological activity of the suprarenal gland." *Id.* at 110.

Hand lumped all other invalidity arguments together as a set of "technical objections" to the patent.[140] The first technical objection was to Takamine's strategy of drafting overlapping claims of various different breadths, which the defendant argued was fraudulent and duplicative. Hand waved off these complaints by noting that "every prudent solicitor ought to" do the same, and expressing sympathy for the plight of the patent drafter steering between the risks of invalidity and too-narrow claiming: "To pass between this Scylla and the Charybdis, I think a patentee may fairly be entitled to bend sails upon many yards."[141]

The second technical objection provided what has become the classic holding of *Parke, Davis*. Defendant had contended that "the patent [was] only for a degree of purity, and therefore not for a new 'composition of matter.'"[142] Hand answered, in the first instance, that Takamine had been the first to isolate from the adrenal gland "a substance which was not in salt form." Given testimony that the active principle existed naturally as a salt, Takamine's production of a base was "a distinction not in degree, but in kind."[143] Famously—and apparently in dicta—Hand then went on: "But, even if it were merely an extracted product without change, *there is no rule that such products are not patentable*. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically."[144]

Hand left no doubt that his reasoning followed the pragmatic, inventor-rewarding rationale of *Kuehmsted*. "Everyone, not already saturated with scholastic distinctions," the judge observed, "would recognize that Takamine's crystals were not merely the old dried glands in a purer state . . . The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic." Concluding the opinion, Hand noted that "Whatever confusion the intricacy of the subject-matter causes, one fact stands out, which no one ought fairly to forget."

> Before Takamine's discovery the best experts were trying to get a practicable form of the active principle. The uses of the gland were so great that it became part of the usual therapy in the best form which was accessible. As soon as Takamine put out his discovery, other uses practically disappeared . . . All this ought to count greatly for the validity of the patent, and Takamine has a great start, so to

[140] *Id.* at 102.
[141] *Id.* at 102-3.
[142] *Id.* at 103.
[143] *Id*.
[144] *Id*. (emphasis added).

> speak, from such facts . . . this is a case where he should be entitled to a lenient construction, for he has been author of a valuable invention and has succeeded where the most expert have failed.[145]

Having upheld Takamine's patents, all that remained for Hand was a comment on the shortcomings of patent adjudication more generally. Warming to the theme of his earlier article on expert testimony, and to his generally technocratic Progressive philosophy, Hand vented his displeasure with the inefficiency of a generalist court being asked to tackle complex scientific problems. "I cannot stop," he wrote, "without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils, for only a trained chemist is really capable of passing upon such facts."[146] Recalling that German courts called on neutral technical advisors to resolve scientific disputes, Hand issued a plea for just one further German import. "How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance."[147]

III. READING *PARKE, DAVIS*

Parke, Davis did not immediately become a "leading case," at least not for the reasons it is now. Hand's decision took a roundabout route to the center of the gene patenting debate. Along the way, the case lost some of its intended meaning.

A. Was Parke, Davis *Rightly Decided?*

The two sides of the gene patenting debate differ over whether *Parke, Davis* was rightly decided.[148] At trial in the *Association for Molecular Pathology* case, the ACLU branded Hand's decision "erroneous" for two

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[145] *Id.* at 114-15.
[146] *Id.* at 115.
[147] *Id.*
[148] *See, e.g.* Myriad Defendants' Memorandum of Law in Support of their Motion for Summary Judgment and in Opposition to Plaintiffs' Motion for Summary Judgment, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, S.D.N.Y, No. 09 Civ. 4515 (December 23, 2010), 3 (hereafter "Defendants' December 23 Memorandum") ("Plaintiffs' . . . argument depends upon convincing this Court that this long and consistent line of authority was the product of legal error after legal error after legal error. For example, plaintiffs say that Learned Hand's holding that a purified natural substance (adrenaline) was patent-eligible subject matter was 'erroneous.'").

reasons. First, because it conflicted with the Supreme Court's holdings in *American Wood-Paper* and *Cochrane v. BASF*.[149] (As other commentators have pointed out, Hand did not even discuss the wood-paper case, other than to note that it had been raised by the Patent Office).[150] Second, the ACLU argued that Hand had been wrong to rely on *Kuehmsted* and *Union Carbide*: these cases were "inapposite" because they dealt with man-made chemicals rather than naturally-occurring substances.[151]

This second argument—call it the "nature is different" theory—falls flat. As discussed above,[152] there was no clear natural/non-natural line in the judicial case law at the time of *Parke, Davis*. The prior decisions on extraction and purification treated these issues as questions of patentable novelty that might apply to any invention. Learned Hand might have chosen in *Parke, Davis* to propose such a categorical distinction, but his failure to do so is not a serious objection to the holding. At most, one could argue that Hand should have adopted and expanded the Commissioner of Patents' decision in *Ex parte Latimer*—not only giving that opinion its first judicial recognition, but extending its holding to substances that had been purified as well as extracted.[153] Again, nothing required him to do so.

The harder question is whether *Parke, Davis* conformed to the Supreme Court's earlier rulings, *American Wood-Paper* and *Cochrane*. Neither was a product-of-nature case *per se*, but each suggested a rule that might bear on products of nature as a class. Both decisions were understood to mean that an old product could not be patented simply because it came from a new source or was obtained by a new process.[154] Applying these decisions to product-of-nature cases essentially meant treating the product-of-nature problem as a subset of the novelty inquiry: the claimed product could not be patented *if* it was in the prior art.[155] However, neither opinion decided where, on the spectrum of changes to the prior art, one should draw the line of patentable novelty. The Court in

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[149] Plaintiffs' Memorandum, *supra* note 15, at 24-25.

[150] *See, e.g.* Richard S. Gipstein, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 1, 21 (2003).

[151] Plaintiffs' Memorandum, *supra* note 15, at 25; Gipstein, *supra* note 147, at 23.

[152] *See infra*, Section II.B.2.

[153] *See infra*, footnotes 67-69 and accompanying text. Recall that *Latimer* applied narrowly to substances that had not been "in any wise . . . affected, changed, or altered," 1889 Dec. Com. Pat at 125, and also left a sizeable exception for substances showing "some new quality or function which it does not possess in its natural condition" *Id.* at 127.

[154] *See infra*, footnotes 72-73 and accompanying text.

[155] Whether natural products are automatically in the prior art is an interesting question. By definition they are old, but prior art in the patent law is not identical with the pre-existing world: there is a knowledge element involved. *See, e.g. Gayler v. Wilder*¸ 51 U.S. (10 How.) 477, 497-98 (1850) (ruling that "lost" prior art did not anticipate a later re-invention). At the same time, courts have not typically accepted mere discovery as grounds for a patent.

American Wood-Paper had "doubted" that a "slight difference" in purity could constitute a new product,[156] but that mild statement left ample room for greater degrees of purification to confer patentability. *Cochrane* had indicated that a synthetic product identical to the prior art substance could not be patented,[157] but said nothing about the degree of variation that would be patentable. Neither case foreclosed the central holding of *Parke, Davis*.

Enter *Kuehmsted* and *Union Carbide*. The reasoning of these cases that a commercially-significant advance in purification constituted a meaningfully new product was a judicial innovation that barely pre-dated *Parke, Davis*. But it was nonetheless valid law, not foreclosed by earlier Supreme Court decisions, and in the case of the Second Circuit's *Union Carbide*, binding precedent for Judge Hand.

This does not mean that Hand's opinion was wholly correct. The notorious line "But, even if it were merely an extracted product *without change*, there is no rule that such products are not patentable"[158] pretty clearly runs afoul of *American Wood-Paper* and *Cochrane*. Furthermore, the statement was dicta: Hand did not construe Takamine's invention as an "extracted product without change."[159] Most bizarrely, the assertion conflicted with the central point of the *Parke, Davis* opinion itself, which was that commercially-transformative purification *did* constitute a change "in kind" that the patent law must recognize. However, as a much-quoted fragment of the *Parke, Davis* opinion,[160] the phrase has made Hand's position sound both broader and less reliable than it actually was.

This is an unfortunate fact of the *Parke, Davis* legacy: patentability via mere extraction was not the crux of the ruling, but has been taken as such thanks to some loose language on the part of the author. Even if he were now around to object, Learned Hand would have only himself to blame.

B. Parke, Davis *as Authority*

Parke, Davis has been cited and quoted as a noteworthy case for a long time, but was not immediately taken up as an authority on products of nature—or even on patent law. The first published work to note the opinion was an article on the constitutionality of labor laws by Learned Hand's friend and fellow progressive, Harvard professor Felix Frankfurter. Frankfurter concluded his appeal for realism in judicial decision-making by calling for "the invention of some machinery by which knowledge of the facts . . . may be at the service of the courts as a regular form of the

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[156] *American Wood-Paper*, 90 U.S. at 594.
[157] *Cochrane*, 111 U.S. at 311.
[158] *Parke, Davis*, 189 F. at 103 (emphasis added).
[159] *Parke, Davis*, 189 F. at 103.
[160] *See, e.g.* Utility Examination Guidelines, *supra* note 8, at 1093.

judicial process."[161] Quoting Hand's plea in *Parke, Davis* for a system of scientific advisors in technical cases, Frankfurter maintained that "[t]his need has been voiced alike by jurists and judges."[162] So began a tradition, which continues to this day, of citing *Parke, Davis* on general questions of judicial expertise and the problems of technical knowledge.[163] As Learned Hand's reputation grew, his call for reform of scientific adjudication came to stand for a further principle: the propriety of judges calling from the bench for statutory change.[164]

Even in patent opinions, *Parke, Davis* did not first appear as a case on patentability. Initial citations focused on Hand's remarks about claim multiplication and the advisability of a patentee drafting claims of various breadths.[165] Only in the 1930s did *Parke, Davis* begin to show up as a precedent on patentable novelty, appearing in long string cites as a case in the *Union Carbide* line (patentable novelty demonstrated by commercial utility).[166] Elsewhere, *Parke, Davis* was conspicuously absent. Federal courts produced a number of decisions in these years that addressed the patentability of products of nature, principally in the context of metals: patents for tungsten, uranium, and ductile vanadium were all rejected.[167] None of these decisions mentioned *Parke, Davis* as a counter-authority.

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[161] Felix Frankfurter, *Hours of Labor and Realism in Constitutional Law*, 29 HARV. L. REV. 353, 372 (1916). On the shared Progressive and legal-realist context in which both Frankfurter and Hand operated, *see* Barry Friedman, THE WILL OF THE PEOPLE: HOW PUBLIC OPINION HAS INFLUENCED THE SUPREME COURT AND SHAPED THE MEANING OF THE CONSTITUTION, 178, 194 (2009).

[162] Frankfurter, *supra* note 158, at 372.

[163] *See, e.g.* Note, *The Federal Trade Commission as Special Master in Anti-Trust Suits*, 30 HARV. L. REV. 168, 170 (1916); Felix Frankfurter, *The Business of the Supreme Court of the United States - A Study in the Federal Judicial System*, 39 HARV. L. REV. 587, 627 (1926); Sidney Post Simpson, *Fifty Years of American Equity*, 50 HARV. L. REV. 171, 251 (1936); *Perkins v. Endicott Johnson Corp.*, 128 F.2d 208, 216 (2d. Cir. 1942); *Marconi Wireless T. Co. of Am. v. United States*, 320 U.S. 1, 80 (1943); *Blonder-Tongue Laboratories, Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 350 (1971); Edward V. Di Lello, *Fighting Fire with Firefighters: A Proposal for Expert Judges at the Trial Level*, 93 COLUM. L. REV. 473, 507 (1993); Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court-and Vice Versa*, 59 AM. U. L. REV. 787, 789 (2010).

[164] *See, e.g. U.S. v. St. Pierre*, 132 F.2d 837, 847 (2d. Cir. 1942); *Audi Vision Inc., v. RCA Mfg. Co.*, 136 F.2d 621, 625 (2d. Cir. 1942); *Watson v. United States*, 979 A.2d 1254, 1268 (D.C. 2009).

[165] *A.B. Dick Co. v. Underwood Typewriter Co.*, 246 F. 309, 313 (S.D.N.Y. 1917); *Vortex Mfg. Co. v. F.N. Burt Co.*, 297 F. 513, 516 (W.D.N.Y. 1924); *In re McConnell*, 40 F.2d 567, 568 (C.C.P.A. 1930).

[166] *United Chromium v. International Silver Co.*, 53 F.2d 390, 394 (D. Conn. 1931); *Donner v. Sheer Pharmacal Corp.*, 64 F.2d 217, 223 (8th Cir. 1933).

[167] *General Electric Co. v. DeForest Radio Co.*, 28 F.2d 641 (3rd Cir. 1928) (tungsten); *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931) (uranium); *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931) (ductile vanadium).

Only at one point[168] did Hand's opinion crop up in a product-of-nature case during the first half of the twentieth century. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.* (1948), the Supreme Court considered the patentability of an inoculant package combining four strains of bacteria, eventually invalidating the patent on product-of-nature grounds.[169] The patent-owner in that case cited *Parke, Davis* in the course of arguing that the combination was "for every practical purpose a new thing."[170] The Court rejected this argument without referring to Hand's opinion.[171]

All of this changed in 1958, with the Fourth Circuit's decision in *Merck & Co. v. Olin Mathieson Chemical Corp.*[172] The *Merck* opinion described a situation strikingly similar to that of *Parke, Davis*. It had long been known that something in cattle livers had therapeutic effects in treating pernicious anemia. In the late 1940s, scientists at Merck succeeded in isolating the active constituent, which they identified as vitamin B-12.[173] As in the case of Parke, Davis and adrenalin, the isolated and purified product quickly supplanted the crude extracts previously on the market.[174] Defendants in *Merck v. Olin Mathieson* argued that the B-12 patent claimed a product of nature, and succeeded in prevailing at the district court on these grounds.[175] The Fourth Circuit reversed, dismissing the notion of a categorical product-of-nature bar and stating that "where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained."[176] Citing *Parke, Davis*

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[168] For these purposes, I am not counting a case in which the product-of-nature question was not presented as such. In *In re King* (1939), a patent applicant claimed purified vitamin C from lemon juice. The Court of Customs and Patent Appeals rejected his claim as anticipated by a 1928 publication in which another scientist had obtained the same substance from animal adrenal glands, cabbage, and orange juice. Although King raised *Parke, Davis* to argue that his purified form was a new therapeutic substance, the court found the case "inapplicable" because "[l]emon juice has been known for ages as a satisfactory specific for scurvy." *In re King*, 107 F.2d 618, 620 (C.C.P.A. 1939).

[169] *Funk Bros.*, 333 U.S. at 130-32.

[170] Brief of Respondent, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 1948 WL 47563 (U.S.), 57 (January 5, 1948) (quoting *Parke, Davis*, 189 F. at 103).

[171] Shortly afterwards, in *Application of Williams* (1940), a patent applicant before the Court of Customs and Patent Appeals argued that "naturally occurring substances, such as we have here, are unpatentable only when such claims are anticipated by the availability of the reference substance." The court did not argue the proposition, but dismissed the applicant's argument on anticipation as unsupported by the facts of the case. *Application of Williams*, 188 F.2d 509, 511 (C.C.P.A. 1951).

[172] 253 F.2d 156 (4th Cir. 1958).

[173] *Id.* at 157-61. Merck obtained the vitamin both as an extract from cattle livers and as the product of micro-organisms (the latter being the process claimed in the patent). *Id.* at 160.

[174] *Id.* at 158.

[175] *Merck & Co. v. Olin Mathieson Chem. Corp.*, 152 F. Supp. 690 (W.D. Va. 1957) rev'd, 253 F.2d 156 (4th Cir. 1958). The court also noted that most of the original product claims in the relevant patent application had been rejected by the Patent Office on product-of-nature grounds. *Id.* at 696.

[176] *Merck & Co.*, 253 F.2d at 162.

"illustratively," but following its reasoning closely, the court upheld the patent based on the troika of *Parke, Davis*, *Kuehmsted*, and *Union Carbide*.[177] The rationale of novelty-through-greater-utility carried the day: "[t]he compositions of the patent here," stated the opinion, ". . . never existed before; there was nothing comparable to them . . . The new products are not the same as the old, but new and useful compositions entitled to the protection of the patent."[178]

Merck marked the arrival of *Parke, Davis* as a standard reference in the case law. At the same time, the *Merck* opinion became the source for the "canon" of standard historical references on product-of-nature patents. Broadly speaking, this featured *American Wood-Paper*, *Cochrane*, the metals cases, and *Funk Bros.* appearing on the anti-patentability side; and *Parke, Davis*, *Kuehmsted*, and *Union Carbide* on the side of patentability for significantly isolated and purified products. *Merck* immediately joined the set of precedents for patenting products of nature, while *Ex parte Latimer* would eventually be discovered by the courts as an anti-patentability authority during the 1970s.[179]

The final piece of the puzzle, of course, was the biotechnology revolution of the late twentieth century. *Parke, Davis* made cameo appearances in the lower courts during the two pivotal genetic engineering cases, *Chakrabarty* and *In re Bergy*. The most forceful reference to Hand's decision appeared in the pro-patentability opinion of Judge Giles Rich on the Court of Customs and Patent Appeals. Rich, the most influential patent judge of his era, asserted that "[t]he law has long and unhesitatingly granted patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found such important products of microbiological process as vitamin B-12 and adrenalin and countless other pharmaceuticals."[180]

The apotheosis of *Parke, Davis* arrived in the 1990s and 2000s, on the heels of the first gene patents.[181] After *Chakrabarty*—where the U.S. Patent and Trademark Office had attempted to hold the line against patenting living organisms on product-of-nature grounds—the PTO's resistance ebbed, and the Office adopted a liberal approach to subject-matter, especially towards claims to "isolated and purified" genetic

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[177] *Id*. at 162-63.
[178] *Id.* at 164.
[179] *See, e.g.* Conley & Makowski, *Part I*, *supra* note 11, at n. 151 (observing that *Latimer* was not cited in judicial opinions until the *Bergy* and *Chakrabarty* cases).
[180] *Application of Bergy*, 596 F.2d 952, 975 (C.C.P.A. 1979) *vacated in part sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) and *aff'd sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[181] On the early phase of patenting for DNA sequences, *see e.g.* Daniel Kevles and Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 Brook. L. Rev. 233 (2001).

material.[182] The product-of-nature doctrine "all but disappear[ed] as a serious concern."[183]

This was the period when *Parke, Davis* became a staple of the law-review literature and a ready shorthand for the PTO's policy. In 2001, after inviting public comments, the PTO issued revised Utility Examination Guidelines that defended and elaborated on its approach to gene patenting. Under the section dealing with the product-of-nature argument, the PTO took pains to point out that "patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice."[184] The Guidelines then gave three examples: a patent for yeast issued to Louis Pasteur in 1873, a 1970 case involving extracted prostaglandins, and—accompanied by extensive quotation—Judge Hand's opinion in *Parke, Davis*.[185]

So, did the PTO get *Parke, Davis* right? Not exactly. Tellingly, the PTO cited Hand's dictum claiming that "no rule" rendered "an extracted product without change" unpatentable. Although the Guidelines also quoted Hand's note that Takamine's adrenalin was "a new thing commercially and therapeutically," the implication was clearly that isolation alone made it so. Under this logic, the Guidelines explained that isolated and purified DNA molecules are patentable (1) if isolated by extraction, because "that DNA molecule does not occur in that isolated form in nature"; and (2) if synthesized in pure form, "because their purified state is different from the naturally occurring compound."[186]

Absent from this analysis was the heart of the *Parke, Davis* holding: that Takamine's product was patentable as an isolated and purified substance *only* because purification delivered a transformative difference in utility between the new product and its natural precursor. For commentators who worry that the Patent Office has come to treat "isolated and purified" as a test in its own right—and to wave through the patentability threshold any patent using that rubric—the attention paid to

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[182] John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine As A Barrier to Biotechnology Patents (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 379-85 (2003). Note that gene patenting is an area where the practices of the U.S. Patent Office have so far proven at least as important as the input of the courts. The reason is connected to the non-adversarial nature of the patent system: rejected applicants appeal to the courts, but those who get their patents do not. As a result, judicial involvement is more intense when the PTO operates a restrictive policy; when the Office pursues permissive patenting practices, it operates with a relatively freer hand. *See, e.g.* Jonathan Masur, *Patent Inflation*, 121 YALE L. J. (forthcoming 2011); John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041 (2011).

[183] *Id.* at 380.

[184] Utility Examination Guidelines, *supra* note 8, at 1093.

[185] *Id*. (citing U.S. Patent 141,072, "Improvement in the Manufacture of Beer and Yeast," issued to Louis Pasteur, July 15, 1873; *In re Bergstrom*, 427 F.2d 1394, 1397 (CCPA 1970)).

[186] *Id*.

Parke, Davis in current litigation is already providing a useful corrective.[187] As Takamine's lawyers themselves had stated before the Patent Office, there could be no patent for a product "unchanged from native condition except that it was withdrawn or abstracted from its natural setting, as a pebble might be picked out of a mud bank."[188]

IV. *PARKE, DAVIS* IN LAW AND HISTORY

A. A New View of Parke, Davis *at the Federal Circuit?*

Back, then, to *Association for Molecular Pathology*, the gene-patent challenge recently decided at the Federal Circuit. There are signs that the appellate litigation process is gradually weeding out some of the historical misconceptions surrounding the product-of-nature bar and its key precedents.[189] Learned Hand's critics also seem to have retreated somewhat: rather than arguing that Hand's decision was erroneous, the ACLU brief on appeal distinguished the case[190] and argued that the opinion's broad dicta were overruled by later decisions.[191] In discussing isolation and purification, the U.S. Government's heavyweight amicus brief placed *Parke, Davis* into proper context alongside *Kuehmsted* to argue that patentability depends on a "difference of kind" rather than on purification *per se*.[192]

Nevertheless, how to treat *Parke, Davis* as a legal authority remains a tricky question for the courts. As a District Court case, not to mention one that preceded a century of appellate product-of-nature decisions, the precedential authority of Hand's opinion is slight. Any strictly doctrinal value derived from the case comes from (a) treating its reasoning as compelling or "illustrative," or (b) arguing that Hand's decision inaugurated and represents a long unbroken tradition of case law.

In either instance, it is important to be clear about what the reasoning of *Parke, Davis* actually was. To repeat: the decision held that

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[187] *See infra,* Part IV. On concerns about the Patent Office's approach, *see, e.g.* Conley & Makowski, *Part II*, *supra* note 179, at 386-87.

[188] Jokichi Takamine, Amendment September 25, 1902, Trial Record at 888.

[189] When discussing the origins of the doctrine, for example, the parties and the Federal Circuit no longer try to cram the always-awkwardly-included American Wood-Paper and Cochrane cases into the discussion. *See, e.g. Ass'n for Molecular Pathology*, slip opinion of Lourie, J. at 39, n. 6 (disregarding these two cases as having been "decided based on lack of novelty, not patentable subject-matter.")

[190] The ACLU distinguished the cases on grounds whose relevance to patentability was dubious: to wit, that "DNA . . . serves as an informational molecule, [whereas] the purified adrenaline was used as a therapeutic, and patents thereon did not impede determination of patient adrenaline levels." Brief of Appellees, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, Fed. Cir. No. 2010-1406 (November 30, 2010), 48.

[191] *Id.* at 48-49.

[192] Brief of the United States as Amicus Curiae, *supra* note 12, at 29-30.

an isolated and purified natural substance could be patentable, *so long as* the greater utility of the purified version made it functionally a new thing. Call this the requirement of "useful difference." Having arguably been disregarded in the Patent Office's approach to gene patenting, this question of useful difference has returned with a bang in *Association for Molecular Pathology*, to become one of the crucial fault-lines along which the Federal Circuit's split opinions divide. One opinion eschews Hand's basic reasoning, while two—on different sides of the result—embody it. The approach that each opinion takes toward *Parke, Davis* thus encapsulates the choices facing the Federal Circuit and/or the U.S. Supreme Court going forward.

Judge Lourie's opinion upholding the BRCA claims[193] rests the patentability of isolated DNA sequences entirely on the nature of the isolation itself. Lourie's starting-point is that isolated DNA sequences are, as a factual matter, "markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature."[194] Extraction itself provides part of the basis for this conclusion, since DNA sequences in their native state are "packaged into the chromosomal structure" via chemical bonds in a way that isolated or synthesized DNA sequences are not. [195] Yet Lourie goes further, arguing that the chemical bonds themselves are part of the nature of the native DNA, such that cleaving them or synthesizing a molecule without them produces a "distinct chemical entity."[196]

With this move, Judge Lourie side-steps the crucial problem for the would-be patentee of a product of nature. If DNA isolation changes the source material, rather than merely abstracting it from its setting, then the case for patentability is vastly easier to establish under the governing Supreme Court precedents: *Funk Bros.*, denying protection to unmodified organisms, is distinguished, while *Chakrabarty*, allowing a patent for a "non-naturally-occurring . . . product of human ingenuity," is satisfied.[197]

It is in this context that *Parke, Davis* makes a guest appearance in Lourie's opinion, as a way to hammer home the distinction between what is and is not a meaningful change from nature. *Parke, Davis*, in the judge's view, is distinguishable as a case about "purification," a categorically different process involving the physical separation of the desired compound from a mixture.[198] By contrast, "the claimed isolated

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[193] Judge Lourie wrote the opinion of the court as to issues of standing and the validity of the patentee's method claims, but wrote for himself alone on the patentability of isolated DNA sequences.

[194] *Ass'n for Molecular Pathology*, slip opinion of Lourie, J., at 41.

[195] *Id*. at 42.

[196] *Id*. at 43-44.

[197] *Id.* At 39-41, quoting *Chakrabarty*, 447 U.S. at 309.

[198] *Id.* at 42-43 ("Accordingly, this is not a situation, as in *Parke-Davis & Co. v. H.K. Mulford Co.*, in which purification of adrenaline resulted in the *identical* molecule being 'for every practical purpose a new thing commercially and therapeutically'").

DNA molecules do not exist as in nature within a physical mixture to be purified," but must be chemically cleaved to become free-standing entities.[199] This distinction is less important than what Lourie *doesn't* do with the case. The central aspect of Parke, Davis—the requirement that some greater utility accompany the change of form—remains absent from Judge Lourie's opinion.

The same is not true of the other voices on the court. Judge Moore, concurring in the result but writing separately, makes "useful difference" the centerpiece of her analysis. For Moore, the test of patentability is the presence of "markedly different characteristics with the potential for significant utility, e.g., an 'enlargement of the range of . . . utility' as compared to nature."[200] In constructing this test, Moore rests on the same Supreme Court precedents as Judge Lourie, *Funk Bros.* and *Chakrabarty*, but reads these cases to emphasize the need for useful difference.[201]

In effect, Moore treats these later Supreme Court decisions as having adopted the reasoning of *Parke, Davis*. For Judge Moore, Learned Hand's opinion represented "an analogous patentability inquiry long before *Funk Brothers* or *Chakrabarty*."[202] Along with *Merck v. Olin Mathieson* (the Fourth Circuit's vitamin B-12 ruling that was a direct descendant of *Parke, Davis*), these cases "weigh the same considerations"[203] and demonstrate a consistent and "longstanding flexible approach."[204] This is, I believe, a new slant on *Funk Bros.* and *Chakrabarty*, neither of which cited *Parke, Davis* or *Merck* or appeared consciously to adopt a "useful difference" standard (despite admittedly suggestive language). In that sense, Judge Moore's opinion should be considered a notable posthumous coup for Learned Hand.

The coup is all the more impressive for capturing a majority of the Federal Circuit panel. Judge Moore applies the useful difference standard to uphold the patent claims at issue in *Association for Molecular*

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[199] *Id*. at 43.

[200] *Ass'n for Molecular Pathology*, slip opinion of Moore, J., at 7, quoting *Chakrabarty*, 447 U.S. at 309-10; *Funk Bros.*, 333 U.S. at 131.

[201] *See, e.g.*, *Ass'n for Molecular Pathology*, slip opinion of Moore, J., at 5:

> *Funk Brothers* indicates that an invention which "serve[s] the ends nature originally provided" is likely unpatentable subject matter, but an invention that is an "enlargement of the range of . . . utility" as compared to nature may be patentable. 333 U.S. at 131. Likewise, *Chakrabarty* illustrates that an invention with a distinctive name, character, and use, e.g., markedly different characteristics with the potential for significant utility, is patentable subject matter. 447 U.S. at 309-310. Although the two cases result in different outcomes, the inquiry itself is similar.

[202] *Id.* at 5.

[203] *Id.* at 21.

[204] *Id.* at 7.

Pathology, finding sufficient new utility in the isolated DNA sequences to sustain their validity.[205] By contrast, Judge Bryson's dissent sides with the District Court in finding the relevant patent claims invalid. The dissent devotes most of its energies to contesting Judge Lourie's notion that isolation meaningfully changes the claimed DNA sequence. Among a series of memorable analogies, Judge Bryson likens the process of gene isolation to "snapping a leaf from a tree."[206] However, Bryson's opinion similarly adopts useful difference as a necessary condition: "the test employed by the Supreme Court in *Chakrabarty* requires us to focus on two things: (1) the similarity in structure between what is claimed and what is found in nature and (2) the similarity in utility between what is claimed and what is found in nature."[207]

This may not be a bad way to apply *Chakrabarty* to the isolated-DNA debate; after all, as Judges Moore and Bryson point out, the 1980 decision does include "distinctive . . . use" alongside "distinctive name [and] character" in separating patentable invention from nature's handiwork.[208] It does, however, mark a dramatic reversal of *Parke, Davis*'s lowly place in the precedential pecking-order: from a mere district court opinion, the decision has retrospectively become a guiding principle of later Supreme Court doctrine. This revived appreciation of Learned Hand's opinion means we should expect to see more of *Parke, Davis* if the gene-patent question proceeds to further review.

B. Parke, Davis *and History*

Parke, Davis has other uses as a tool of legal argument. Because patentable subject matter is traditionally a judge-made, common-law area,[209] the courts will likely continue to look to the history of patent practice for guidance. This is what happened, for example, in the recent business-method case *Bilski v. Kappos*, where much ink was spilled over the question of whether similar patents had historically been issued in

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[205] *Id.* at 15-19. Judge Moore finds the claims to short isolated DNA sequences to have ample "applications and uses in isolation that are new and distinct as compared to the sequence as it appears in nature." *Id.* at 15. Claims to longer DNA sequences are a closer case: "If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter. Despite the literal chemical difference, the isolated full length gene does not clearly have a new utility and apppears to simply serve the same ends devised by nature." However, the settled expectations of an inventing community long used to obtaining gene patents "tip the scale in favor of patentability." *Id.* at 18-19.

[206] *Ass'n for Molecular Pathology*, slip opinion of Bryson, J., at 10.

[207] *Id.* at 12.

[208] *Ass'n for Molecular Pathology*, slip opinion of Moore, J., at 4; opinion of Bryson, J. at 12 (both quoting *Chakrabarty*, 447 U.S. at 309-310, which in turn was quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

[209] *See infra*, note 17.

Britain and the United States.[210] In this vein, *Parke, Davis* has been and will continue to be treated by some as evidence that the United States has "long and unhesitatingly granted patent protection" to similar substances.[211] As Judge Moore put it in *Association for Molecular Pathology*, "The settled expectations of the inventing community with respect to isolated DNA claims are built upon [*inter alia*] . . . judicial precedent, such as *Parke-Davis* and *Merck*." On the other side, the case will likely continue to be branded as a historical outlier or an error.[212]

The balance of truth in such statements can only fully be judged by trawling through the vast record of issued patents and patent applications. Even then, we would be unlikely to find evidence of a long-lasting consensus practice one way or the other. It is well known, for example, that courts rejected patents for purified metals on unambiguous product-of-nature grounds in the 1920s and 1930s. Equally true, however, is that the Patent Office continued to grant patents for hormones.[213] Anyone looking for a historical "right" answer on the product-of-nature question will probably be disappointed.

Even so, *Parke, Davis* may still speak to us from history. Formal legal doctrine aside, the events described in this story left their mark on the medical and scientific world in which they arose. John J. Abel, the pioneer of academic pharmacology who clashed with Takamine as a possible discoverer of adrenalin, came away from the experience with a pronounced suspicion of commercialized science. Perhaps not coincidentally, he became a leading opponent of patenting within the scientific establishment: his American Society for Pharmacology pointedly joined the AMA's opposition to drug patenting and excluded industrial chemists at its founding in 1908.[214] Abel's position was increasingly in the minority, however. In the shadow of the *Kuehmsted* and *Parke, Davis* litigation, the distance between "ethical" pharmaceuticals and patented medicines dissolved. The courts observed

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[210] *Bilski v. Kappos*, 130 S. Ct. 3218, 3239-50 (2010) (concurrence of Stevens, J); *In re Bilski*, 545 F.3d 943, 966-76 (Fed. Cir. 2008) (concurrence of Dyk, J.); *id.* at 986-94 (concurrence of Newman, J.).

[211] *Application of Bergy*, 596 F.2d at 975.

[212] *See, e.g.* Demaine & Fellmeth, *supra* note 43, at 339-45.

[213] *See, e.g.* U.S. Patent 1,218,472, "Growth-controlling substance derived from the anterior lobe of the pituitary gland and process for producing the same," issued to T. Brailsford Robertson, March 6, 1917; U.S. Patent 1,392,767 "Thyroid Product and Process of Preparing the same," issued to University of Minnesota as assignee of Edward Kendall, October 4, 1921; U.S. Patent 1,469,994, "Extract obtainable from the mammalian pancreas," [insulin] issued to F. D. Banting, October 9, 1923. *See also* Maurice Cassier & Christine Sindig, *Patenting in the Public Interest: Administration of Insulin Patents by the University of Toronto*, 24 HIST. & TECH. 153 (2008); Dutfield, *supra* note 29, at 104-31.

[214] PARASCANDOLA, *supra* note 93, at 115.

no distinction.[215] The organized medical profession wavered.[216] Research scientists began to learn, and to share, the lessons of biomedical patenting.[217]

Most poignantly, the H.K. Mulford Company yielded. Mulford began the adrenalin suit by announcing "that in defending these suits it has consistently and at great cost endeavored to uphold its antagonistic position toward the product patent for medicinal substances, believing that product patents on all substances used in medicine work an injustice on the medical and pharmaceutical professions and are inimical to the public good."[218] The year after Hand's decision, though, Mulford abandoned its pledge and began to seek product patents.[219] Within a few more years, the American pharmaceutical industry's patent drive was in full swing. Standing at the threshold of these events, the *Parke, Davis* story reminds us that an intellectual property culture is not inevitable, but develops piece by piece. Learned Hand's decision a century ago was another brick in the wall.

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[215] *See, e.g.*, *Kuehmsted*, 179 F. at 702 (recognizing patented aspirin as an "ethical remedy").

[216] An AMA committee recommended in 1909 that the Association dispense with its stance against product patents. Gabriel, *supra* note 35, at 171.

[217] The team at the University of Toronto that patented insulin in 1922 looked to Takamine's patent as a precedent. They also received direct patent-drafting and patent-management advice from Edward Kendall, who had once been Parke, Davis's chief adrenalin researcher and later, while at the Mayo Clinic, was responsible for the isolation and patenting of thyroxin. *See* Cassier & Sindig, *supra* note 194, at 154-55. On the scientists who worked to make patenting respectable (several of whom were employed at Parke, Davis and/or Mulford), *see also* Gabriel, *supra* note 35.

[218] "The Adrenalin Patents Valid," 29 PRACTICAL DRUGGIST AND PHARMACEUTICAL REVIEW OF REVIEWS 54 (June, 1911) (Under heading "Statement of H.K. Mulford Co.").

[219] Liebenau, *supra* note 22, at 64.