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Christopher Beauchamp
Brooklyn Law School, christopher.beauchamp@brooklaw.edu

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PATENTING NATURE: A PROBLEM OF HISTORY

Christopher Beauchamp*

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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 DNA sequences 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 article explores the history in question. It traces the patent law's changing treatment of "products of nature" in an attempt to untangle the origins of present-day patentability arguments. The evidence suggests that the historical foundations of the bar on patenting products of nature are surprisingly shaky.

The article also reveals how isolated biological materials first came to be patented. This task, I argue, requires looking not only to court decisions, but also to the history of patent practice. My principal 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.* 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 article 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 play a major role in resolving the gene patent question.*

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* Assistant Professor of Law, Brooklyn Law School. The author is grateful for the thoughts of Derek Bambauer, Frederic Bloom, Anisha Dasgupta, Rochelle Dreyfuss, Robin Effron, Daniel Hulsebosch, Osagie Imasogie, Daniel Kevles, Brian Lee, Irina Manta, Michael Risch, Joshua Sarnoff, Katherine Strandburg, Kara Swanson, Jane Yakowitz Bambauer, and participants in the NYU Law School Innovation Policy Colloquium and in junior-faculty workshops at Fordham and Brooklyn Law Schools. A Brooklyn Law School Dean's Summer Research Stipend supported research for the project.

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. After all, the Patent Act requires "novelty,"[1] a criterion that one might expect to exclude (for example) genes carried by generations of our own ancestors. In addition, the subject-matter provisions of the Act have been described as covering inventions "made by man."[2] DNA sequences identical to those found in nature, whether isolated or not, might seem to stretch the definition of what is human-made. At the same time, a long

1. 35 U.S.C. § 102 (2012).

2. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (contemplating protection for "anything under the sun that is made by man") (quoting S. REP. No 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess., p. 6 (1952)). 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., p. 6 (1952).

line of cases rejects patents for "natural" artifacts. Courts and the Patent Office have invalidated claims for extracted plant material,[3] for purified forms of naturally-occurring metals,[4] and for new combinations of bacteria,[5] 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.[6]

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 rendered free from associated materials have been recognized as patentable in an almost equally long line of cases. Such products, the theory goes, do not exist in their isolated form in nature, and have properties not found in the natural form of the material.[7] This logic 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. Thousands of gene patents have issued under the isolated-and-purified rubric in the past twenty years.[8]

Now, however, the patentable status of isolated DNA sequences hangs in the balance. The U.S. Supreme Court is currently considering *Association for Molecular Pathology v. Myriad Genetics*, a challenge to the validity of two patents relating to two human genes. The *Myriad* case has thus far been a succession of unexpected developments. First, Judge Sweet of the U.S. District Court for the Southern District of New York jolted the biotechnology world by

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3. *Ex parte* Latimer, 1889 DEC. COMM'R PAT. 123.

4. 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); *In re* Marden, 47 F.2d 958 (C.C.P.A. 1931).

5. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

6. *See, e.g.*, 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02(7), at 7-20 (2003).

7. 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.").

8. *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) [hereinafter *Ass'n for Molecular Pathology I*] (citations omitted) ("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"). 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*, 2 IP THEORY 1 (2011).

holding the claims invalid.[9] Then, a further shock: the United States government entered the fray as *amicus curiae* on appeal to argue that isolated genomic DNA is not patentable after all.[10] *Myriad* thus became a contest of usually-irresistible forces in patent law: on one side the weight of the federal government's position[11] and on the other the settled expectations of the inventing community and the enormous vested interests of the patent-holding biotechnology sector.

Perhaps reflecting these contrary pressures, the Federal Circuit produced a split decision: a 2-1 vote to uphold the claims relating to isolated DNA sequences, but with all three judges on the panel advancing different standards for patentability.[12] Amid these splintered opinions, the doctrine permitting isolated gene patents arrives at the Supreme Court in disarray, and with its future in doubt.

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 *Myriad* suggested as much, with the patentees laying claim to "almost 100 years of jurisprudence" supporting patentability[13] and plaintiffs citing "long-established Supreme Court precedent," going back to the nineteenth century, to the contrary.[14]

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9. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

10. Brief of the United States as Amicus Curiae in Support of Neither Party, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (Fed. Cir. 2010) (No. 2010-1406); Alison Frankel, *Amicus Shocker: DOJ Opposes PTO Policy, Says Genes Not Patentable*, THE AMERICAN LAWYER, Nov. 4, 2010.

11. The U.S. government's advocacy typically exerts remarkable influence on courts' patent policy decisions. *See* Colleen V. Chien, *Patent Amicus Briefs: What the Courts' Friends Can Teach Us About the Patent System*, 1 U.C. IRVINE L. REV. 397 (2011) (noting that between 1989 and 2009 every single amicus brief authored by the United States in a Supreme Court patent case, with one exception, predicted the case outcome); John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518 (2010).. Unusually in *Myriad*, the government's litigating position diverged from the apparent preferences of the U.S. Patent and Trademark Office. PTO attorneys pointedly did not appear on the United States' amicus brief.

12. *Ass'n for Molecular Pathology I*, *cert. granted and decision vacated*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), *remanded as* Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) [hereinafter *Ass'n for Molecular Pathology II*].

13. Myriad Defendants' Memorandum in Reply to Plaintiffs' Opposition to Myriad Defendants' Motion for Summary Judgment at 23, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y 2010) (No. 09 Civ. 4515), 2010 WL 1048411 [hereinafter "Defendants' January 29 Memorandum"]. *See also Ass'n for Molecular Pathology II*, 689 F. 3d. at 1347 (Moore, J., concurring) ("There is a century-long history of affirming patent protection for isolated and purified biological products ranging from hormones to vitamins to proteins to antibiotics.").

14. Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment at 19, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181

The historical range of this dispute is not merely ornamental, 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.[15] Among patent doctrines, the question of patentable subject matter is perhaps the area of the law most shaped by non-statutory common-law edicts.[16] And within this area, both the product-of-nature 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. Given the scale of the interests at stake, policy considerations of some kind will likely drive the outcome of the gene-patent litigation. But the historical cases will almost certainly be used to supply an account of why the chosen result is conceptually coherent and continuous with earlier practice. If the reasoning of those opinions is twisted or truncated in the process, then the result will be less clarity rather than more. The article that follows thus aims to untangle the history at issue.

My vehicle for doing so is one of the foundational cases in the gene patenting debate: *Parke-Davis & Co. v. H. K. Mulford Co.*[17] In this case, decided in 1911, the celebrated judge Learned Hand upheld a patent for isolated 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 isolated genetic material. For opponents, Hand's opinion represents an erroneous—and 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,"[18] having been cited in more than two hundred law review and

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(S.D.N.Y 2010) (No. 09 Civ. 4515), 2009 WL 3269113 [hereinafter "Plaintiffs' Memorandum"].

15. Among recent Supreme Court cases see: Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010) (citing Le Roy v. Tatham¸ 55 U.S. 156 (1852)); Quanta Computer, Inc. v. LG Elec., Inc., 553 U.S. 617, 618 (citing Bloomer v. McQuewan, 55 U.S. 539 (1852)); KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 405 (2007) (citing Hotchkiss 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)).

16. 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*, 130 S. Ct. at 3226; 35 U.S.C. § 101 (2012). *See 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 A. 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).

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

18. ROBERT MERGES & JOHN F. DUFFY, PATENT LAW: CASES AND MATERIALS 112 (4th

periodical articles in the last twenty years.[19]

The history of *Parke-Davis* is, in many ways, the key to the history of the product-of-nature question. Four perspectives on the case illuminate the broader issue. First, *Parke-Davis* exemplifies a central historical challenge for thinking about patentable subject matter: the problem of translating the older case law (which the courts insist still applies) into the modern doctrinal framework.[20] The current notion of a stand-alone patentable subject matter requirement does not map well onto the older cases, which intertwined issues of novelty, utility, and inventiveness—all now treated as separate conditions of patentability. Much of the current struggle to define the subject matter requirement turns on whether it should be allowed to incorporate (explicitly or implicitly) aspects of patent law's other policies. *Parke-Davis*, as a crucial instance of the older form of blended reasoning, exposes that dilemma for modern interpreters of the law.

Second, *Parke-Davis* lays bare the development of the product-of-nature doctrine and its exception for isolated materials. In particular, the case reveals what the law of natural-product patents was—or wasn't—following its supposedly formative period in the late nineteenth century. Contrary to common assumption, the prohibition on patenting "natural" items as such was not clearly established at the time. Both the *Parke-Davis* litigation and the history of the adrenalin patent at the Patent Office show the lack of a clear line between natural and non-natural artifacts in patent law, undercutting any easy assumption about the immemorial origins of that distinction.[21]

Third, *Parke-Davis* reveals a story about the actual practices of patenting. This history itself has a kind of legal authority. Because patentable subject matter is traditionally a judge-made, common-law area, the courts consistently look to the history of patentee behavior for guidance about what the law was.[22] The adrenalin case shows a much more mixed picture than decisional law alone would suggest. Before *Parke-Davis*, in the late nineteenth and early twentieth centuries, at least some patents issued for materials merely extracted from natural sources. After *Parke-Davis*, the practice escalated. Victory for the adrenalin patent provided the template for hormone patenting, a watershed in both biomedical research and in patent practice. *Parke-Davis* thus became the gateway to patenting isolated biological substances in the twentieth century—

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ed. 2007).

19. *See* Westlaw database search, KeyCite citing references to *Parke-Davis*, from 1911 to Feb. 15, 2013.

20. *See infra* Part II.A.

21. *See infra* Parts III.A, B.

22. This is what happened, for example, in the recent case of *Bilski v. Kappos*, where much ink was spilled over the question of whether business-method or business-method-like patents had historically been issued in Britain and the United States. 130 S. Ct. 3218, 3239-50 (2010) (Stevens, J., concurring). *See also In re* Bilski, 545 F.3d 943, 966-76 (Fed. Cir. 2008) (Dyk, J., concurring); *id.* at 986-94 (Newman, J., concurring).

despite a turn against product-of-nature patents in the courts just a few years later.[23]

Finally, the decision has had a strange and instructive career as precedent. Learned Hand's opinion largely lay dormant in the first half of the twentieth century, when the courts adopted a broadly skeptical line against patents and the boundaries of patentability. In the second half of the century, however, it re-emerged as persuasive authority on patentable subject matter, and in the last few decades it has taken on the status of a leading case. Most recently, *Parke-Davis* has moved to the center of the gene patent litigation—although not so much in letter as in spirit.[24]

For all these reasons, *Parke-Davis* is a suitable lens through which to view the historical development of product-of-nature patenting. One strand of this article will trace the patent law's changing treatment of products of nature, beginning with several problematic nineteenth-century precursors, picking up with Judge Hand's decision and its place in the genesis of natural-product patenting, and continuing through its doctrinal legacy in the twentieth and early twenty-first centuries. The other strand of the article follows a different, but related theme: an investigation of the cultures and practices of intellectual property. In the context of product-of-nature patenting, such an exercise takes us back into an unfamiliar world. The crucial steps towards patenting isolated biological material took place at a time when patenting in the life sciences looked very different, and the U.S. pharmaceutical industry was positively reluctant to employ product patents as a business tool. That changed, and changed rapidly, right around the time of the adrenalin case. The story of *Parke-Davis* is a window into the process of change.

The approach of the article is thus a mixture of intellectual genealogy and contextual history. Part II briefly lays out the historical challenges plaguing the gene-patent question and the law of patentable subject matter generally. Part III seeks out the origins of the prohibition on patenting products of nature, finding them less secure than one might think. Parts IV and V home in on the early twentieth century, when the foundations for later law and practice began to be laid: first reconstructing the legal, scientific, and commercial setting of biomedical patenting, and then using the adrenalin case to rethink the state of the law at that time. Part V steps back to follow transformations in patent practice and patent law after *Parke-Davis*. The article concludes by returning to the *Myriad* case, and offering some observations on the implications of this history for the gene patenting debate.

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23. *See infra* Parts VI.A, B.
24. *See infra* Part VI.B.

I. PATENTABLE SUBJECT MATTER AND THE PROBLEM OF HISTORY

The current state of patentable subject matter doctrine is messy, to say the least. A "swamp of verbiage . . . [a] murky morass,"[25] and "the 'substantive due process' of patent law"[26] are some of the epithets recently applied to the topic. Some of the confusion arises from the role played by history in this area of the law.

A. *Patent Law 101*

Section 101 of the patent statute makes eligible for patenting "any new and useful process, machine, manufacture, or composition of matter."[27] This wording has been constant since the 1793 Patent Act, except in replacing the archaic term "art" with its modern equivalent, "process."[28] No explicit subject matter exclusions are listed. The law of *unpatentable* subject matter—the universally-acknowledged prohibition on patents for "laws of nature, physical phenomena, and abstract ideas"[29]—thus arises entirely from judicial pronouncements.

This fact creates some knotty problems when it comes to interpreting precedent. The current statutory scheme, laid out in 1952, divides the requirements of patentability neatly into separate conditions: patent-eligible subject matter (found in 35 U.S.C. §101); utility (§101); novelty (§102); nonobviousness (§103); and sufficiency of disclosure (§112). In pre-1952 cases, however, these prerequisites tangled, merged, and overlapped with each other. A court could invalidate a claim based on a newly discovered natural principle on the grounds that the patent lacked sufficient "invention" (or what we would today call nonobviousness).[30] Elsewhere, judges could find a product sufficiently novel for patenting because it possessed a powerful new utility.[31] Absent a requirement to separate considerations of novelty, eligibility, utility, and inventive creativity, courts generally did not do so. Because many of the leading cases on patentable subject matter are blended decisions of this kind, it

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25. MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1260 (Fed. Cir. 2012).

26. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1073 (Fed. Cir. 2011) (Rader, J., concurring).

27. 35 U.S.C. § 101 (2012).

28. Patent Act of 1793, 1 Stat. 318-23. The 1793 Act replaced the first U.S. Patent Act of 1790, which allowed patents for "any art, manufacture, engine, machine or device." Patent Act of 1790, 1 Stat. 109-12. "Process" entered the statute in 1952. *See* Act of July 19, 1952, ch. 950, Pub. L. No. 82-593, 66 Stat. 792, § 101.

29. Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

30. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131-32 (1948).

31. *See, e.g.*, Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 F. 887, 890 (C.C.N.D. Ill. 1909); *see also* the discussion in Part III.C *infra*.

can be hard to discern the true contours of the doctrine.

There are a couple of possible approaches to this situation. One is to suggest that, as a historical matter, there is really no such thing as a doctrine of unpatentable subject matter. In this view, all of the canonical cases can be explained in terms of other patentability requirements: lack of novelty, invention, adequate disclosure, and so on.[32] This argument has much to recommend it, not least a sense of blessed relief: if we were to write the non-statutory exclusions out of the patent law, and apply other criteria with sufficient rigor, we could potentially leave unpatentable the things that are currently thought unpatentable while freeing ourselves of the "confused and inconsistent jurisprudence of patentable subject matter."[33]

That is not going to happen, however. In its most recent statement on the subject, the Supreme Court declared that "[t]he relevant cases rest their holdings upon section 101, not later sections," and that "to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do."[34] The Court refuses to "make the 'law of nature' exception to § 101 patentability a dead letter," as such an approach "is . . . not consistent with prior law."[35]

The Court's commitment to a stand-alone subject matter requirement as a matter of "prior law" creates follow-on historical challenges. Patentees and the lower courts must parse the mixed reasoning of the older cases in order to divine the scope of the § 101 exclusions. One strand of patent law, long curated by the late Judge Giles Rich (a drafter of the 1952 Act), has insisted on a strict separation between the functions and content of novelty, nonobviousness, utility, and patent-eligible subject matter.[36] This rigid separation has proved difficult to maintain in the face of either the case law or the particular challenges of the § 101 cases.[37] The alternative is to accept that patentable subject matter is a traditionally blended inquiry, and not to shy away from

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32. Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591 (2008).

33. *Id*. at 591.

34. Mayo Collaborative Services v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303-04 (2012).

35. *Id.* at 1303.

36. *See, e.g.*, *In re* Bergy, 596 F.2d 952, 960-64 (C.C.P.A. 1979) ("Achieving the ultimate goal of a patent under those statutory provisions involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103"); *see also* Diamond v. Diehr, 450 U.S. 175, 189-90 (1981) (citation omitted) (noting that while it had been argued that "novelty is an appropriate consideration under § 101," "[t]he question . . . of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter'").

37. *See, e.g.*, *Mayo*, 132 S. Ct. at 1304 ("We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap"); *see also* Duffy, *supra* note 16 (detailing the struggles of patent-eligibility provisions based on rules rather than flexible standards).

incorporating concepts of novelty, utility, and inventiveness into it. As I will suggest in this article, considering the historical case law in its own terms nudges us in that direction.

B. *Problems of Nature*

As the courts edge towards a resolution of the § 101 product-of-nature question, both the parties and the bench have proven unable to escape the gravitational pull of the older case law. The district court in *Myriad* noted Judge Rich's admonition that "statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute."[38] Even so, nobody involved has shown an inclination to limit the terms of argument to post-1952 concepts. Several questions result.

One is where the prohibition on patenting products of nature comes from. For opponents of the isolated DNA patents, the answer lies in a "clear line of Supreme Court precedent and accompanying lower court authorities, stretching from *American Wood-Paper* [in 1879] through to *Chakrabarty* [in 1980]."[39] Briefly, the canon of precedent deployed against patentability runs like this: a pair of Supreme Court cases from the late nineteenth century purportedly dealing with purification of natural materials; a decision by the Commissioner of Patents in 1889, *Ex parte Latimer*, rejecting a patent for extracted plant fiber; a clutch of cases from the 1920s and 1930s rejecting patents for pure metals; and three further Supreme Court decisions: *American Fruit Growers v. Brogdex* (1931), rejecting a patent for fruit treated with mold-resistant coating, *Funk Brothers v. Kalo Inoculant Co.* (1948), invalidating a patent for a combination of natural bacteria, and *Diamond v. Chakrabarty* (1980), approving a patent for a man-made bacterium. Later sections of this article will consider the provenance and solidity of this canon. It is fair to say that the oldest cases, at least, provide a shaky foundation for the "product of nature" doctrine.

A converse question is where the exception for isolated natural materials comes from. Perhaps the central fact-on-the-ground of the *Myriad* litigation is that patents *have* been issued—in large numbers—on isolated DNA and on other isolated natural substances: indeed, for one member of the *Myriad* Federal Circuit panel, the "settled expectations of the inventing community" based on "arguably a century or more" of PTO policy were a decisive factor in upholding isolated-DNA patents.[40] So: is this history of practice correct? And how did it begin? At trial, the patent holder, Myriad Genetics, answered with a

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38. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 220 (quoting *In re* Bergy, 596 F.2d 952, 959 (C.C.P.A. 1979)).

39. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 227.

40. *Ass'n for Molecular Pathology II* at 16-17.

venerable authority: *Parke-Davis & Co. v. H. K. Mulford Co.*[41] Starting with this "seminal" decision, a "long and unbroken line of authority" stretched across "100 years of jurisprudence" to the present day, affirming patentability of isolated natural materials that met the criteria of being new and useful.[42] When asserting the consistency of *Parke-Davis* with subsequent Supreme Court decisions, Myriad made sure to underline the expertise of its author, Judge Learned Hand. Hand, in the words of Judge Rich no less, "knew as much patent law as any judge ever has."[43]

All these arguments might once have qualified as conventional wisdom in the patent community, but none of them found favor with the court. Judge Sweet declined to read *Parke-Davis* as a patentable subject matter decision, viewing it as a case that turned on novelty.[44] In any case, the judge declared, the whole isolation-and-purification line that allegedly descended from *Parke-Davis* was suspect: "[m]any . . . including scientists in the fields of molecular biology and genomics, 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."[45] In both the view of Myriad and that of its critics, *Parke-Davis* thus has the distinction of emerging as a foundational moment—though whether as an original innovation or an original sin depends on the speaker. As we shall see, the truth of this claim is mixed, in ways that those citing *Parke-Davis* have not appreciated. Learned Hand's opinion was not much of a legal innovation; nor, for a long time, was it a widely cited precedent in patent law—yet it *was* a formative moment in patenting practice.[46]

Finally, there is the question of what to do with the Supreme Court's recent decision on patenting nature, *Mayo v. Prometheus*.[47] The patent in *Mayo* claimed a method of medical treatment, consisting simply of responding to certain observed natural correlations in patients' metabolite levels after a drug injection. The Court decided unanimously that patents effectively claiming a

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41. *See, e.g.*, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 224 (noting that "Myriad has relied heavily on the holding of the Honorable Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*").

42. *Ass'n for Molecular Pathology*, Defendants' January 29 Memorandum at 1, 23.

43. *Ass'n for Molecular Pathology*, Defendants' December 23 Memorandum at 3, n.1 (citing Giles S. Rich, *The Vague Concept of "Invention" as Replaced by Sec. 103 of the 1952 Patent Act*, 46 J. PAT. OFF. SOC'Y 855, 860 (1964) (republished in 14 Fed. Cir. B.J. 147, 155 (2004)).

44. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 225. Judge Sweet also gently deflated the reverence for Learned Hand expressed in Myriad's briefs. *See id*. at 225, n.46.

45. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 185 (quoting John M. Conley & Roberte Makowski, *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)).

46. *See infra* Part VI.D.

47. Mayo Collaborative Services v. Prometheus Lab., Inc., 132 S. Ct. 1289 (2012).

law of nature are invalid. The justices grounded their reasoning heavily in *stare decisis*,[48] albeit while approving the rationale (avoiding "monopolization" of "basic tools of scientific and technological work") that they found ubiquitous in the case law.[49] Strikingly, the hundred-and-fifty-year line of authorities cited for a prohibition on patenting *laws* of nature is quite different from the group of decisions believed to bar patents on *products* of nature. Another challenge for the DNA-patent litigation is thus to figure out how these ancient lines of jurisprudence do or do not relate to each other.

II. SEARCHING FOR THE ORIGINS OF THE PRODUCT-OF-NATURE DOCTRINE

A. *The Unpatentability of Natural Laws and Principles*

American courts resolved early on that "laws of nature"—including scientific theories, laws of physics, and other fundamental relationships of the natural world—could not be the basis of a patent. The question arose as a matter of patent scope. English judges in the late eighteenth century had extensively debated the question of whether a patent covered only a particular machine, or protected a more abstract concept, "the invention," defined by the mode or principle that the inventor had put into effect.[50] At its outer limit, this act of abstraction raised the troubling thought that a broad enough "principle" of operation might be tantamount to claiming the scientific theory of the invention, or even the natural forces underlying its working. Laws of nature were thus implicated in what one scholar has called the "levels of abstraction problem" characteristic of patent law.[51]

In English law, the *locus classicus* of this issue was the litigation over James Watt's pathbreaking steam engine patent. Watt's assertion that his invention consisted of certain "principles"[52] prompted several judges to announce that "the organization of a machine may be the subject of a patent,

48. *Mayo*, 132 S. Ct. at 1302 (stating that "[t]he presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply *reinforces* our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent" (emphasis added)).

49. *Mayo*, 132 S. Ct. at 1293.

50. Oren Bracha, *Owning Ideas: A History of Anglo-American Intellectual Property* 433-35 (June 2005) (unpublished S.J.D. dissertation, Harvard Law School) (on file with the University of Texas Law Faculty).

51. Tun-Jen Chiang, *The Levels of Abstraction Problem in Patent Law*, 105 NW. U. L. REV. 1097 (2011).

52. Boulton v. Bull, 2 H. Bl. 463, 465, 126 Eng. Rep. 651, 652 (C.P. 1795) (quoting the patent as follows: "my method of lessening the consumption of steam, and consequently fuel in fire engines, consists of the following principles . . ."); *see also* Eric Robinson, *James Watt and the Law of Patents*, 13 TECH. & CULTURE 115, 119-20 (1972).

but principles cannot."[53] "If the principle alone be the foundation of this patent," wrote Mr. Justice Buller, "it cannot possibly stand. . . . The effect, the power, and the operation of steam, were known long before the date of this patent."[54] For those judges who chose to read Watt's patent as one for a "mere principle," some mixture of indistinctness ("it seems impossible to specify a principle") and lack of true novelty thus stood in the way of such a broadly-drawn right.

In the United States, a generally more receptive attitude toward patent grants led courts to accept protection that encompassed the "principle" of the invention.[55] Nevertheless, leading voices in early American patent law took care to specify the limiting line drawn around this concept. Justice Joseph Story, a major architect of patent jurisprudence,[56] stated that "the thing to be patented is not a mere elementary or intellectual discovery, but a principle put in practice, and applied to some art, machine, manufacture, or composition of matter."[57] Thus, for example, no patent could issue for "the admeasurement of time, or the expansive operations of steam."[58] Oliver Evans, one of the most assertive and high-profile patent-owners of the early Republic,[59] similarly placed off-limits "*[t]he eternal, immutable laws of nature, or nature's God*; viz. gravity, attraction, repulsion, adhesion . . . heat, light, electricity, galvanism, magnetism . . . &c. &c. &c." on the grounds that they "cannot be invented or created by man; they have co-existed with eternity; and are *common stock*."[60] In the 1830s, one of the first treatise-writers to outline American patent law took it as axiomatic that "[a]ll the abstract philosophical truths that have been discovered, are free from the patent laws, as are the general powers and qualities of matter."[61]

Two things bear mention about this prohibition on patenting laws of nature. The first is that the bright line—between an unpatentable natural principle and

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53. *Boulton*, 2 H. Bl. at 482 (Heath, J.).

54. *Id.* at 485-86 (Buller, J.).

55. Bracha, *supra* note 50, at 440-42. After 1836, the patent statute explicitly invoked principles in describing the claim requirement: "in case of any machine, [the inventor] shall fully explain the principle and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions." Patent Act of 1836, 5 Stat. 117, § 6.

56. *See e.g.*, Frank D. Prager, *The Influence of Mr. Justice Story on American Patent Law*, 5 AM. J. LEGIS. HIST. 254 (1961); Frank D. Prager, *The Changing Views of Justice Story on the Construction of Patents*, 4 AM. J. LEGIS. HIST. 1 (1960).

57. Earle v. Sawyer, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825).

58. Whittemore v. Cutter, 29 F. Cas. 1123, 1124 (C.C.D. Mass. 1813); *see also* Bracha, *supra* note 50, at 440.

59. P.J. Federico, *The Patent Trials of Oliver Evans* (pts. 1 & 2), 27 J. PAT. OFF. SOC'Y 586, 657 (1945).

60. OLIVER EVANS, EXPOSITION OF PART OF THE PATENT LAW BY A NATIVE-BORN CITIZEN OF THE UNITED STATES 12-13 (1816) (emphasis in original).

61. WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS 110 (1837).

a legitimately patentable application of that principle—proved not to be a clear boundary in practice.[62] In a series of nineteenth-century cases involving broad patent claims, the courts split as to whether particular patentees had crossed the threshold of permissible abstraction. Across technologies ranging from reaction water-wheels[63] to lead-pipe-making[64] to the telegraph[65] and telephone,[66] judges struggled to decide whether broad patents covered concrete applications, or were drawn so broadly that they monopolized natural properties of fluid mechanics, metallurgy, or electro-magnetism. These cases produced some ringing declarations of what could not be patented, such as that in *Le Roy v. Tatham* (1853):

> A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known.[67]

Conversely, judges who sought to uphold similar patents stressed the inventors' new and practical harnessing of nature's properties:

> [W]here a person discovers a principle or property of nature, or where he conceives of a new application of a well-known principle or property of nature, and also, of some mode of carrying it out into practice . . . he is entitled to protection.[68]

In their apparent consensus about the unpatentability of "nature," then, the courts only underlined the difficulty of establishing where the laws of nature ended and the applications of human ingenuity began.

A second point relates to the reasoning behind the prohibition on patenting natural phenomena. Two types of justification recurred in the cases. One was the pre-existence of natural truths, which were thus neither novel when discovered nor human inventions in themselves.[69] By far the more common reason, though, was the danger of over-broad monopoly.[70] As Justice Levi Woodbury put it, patenting any principle at a high level of abstraction would "halt and bar all further advances on the same subject. It would petrify everything as it stood, to the great loss of mankind . . . It would also render the first improver a monopolist, and exclude the exercise or reward of further

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62. *See* Bracha, *supra* note 50, at 448-71.

63. Parker v. Hulme, 18 F. Cas. 1138 (C.C.E.D. Pa. 1849).

64. Le Roy v. Tatham, 55 U.S. 156 (1852).

65. O'Reilly v. Morse, 56 U.S. 62 (1853).

66. The Telephone Cases, 126 U.S. 1 (1888).

67. *Le Roy v. Tatham*, 55 U.S. at 175.

68. *Id*. at 185.

69. Although the background assumptions of this view were largely unstated, Joshua Sarnoff has argued that they drew on religious understandings of nature and creation: *see* Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 HASTINGS L.J. 53, 84-90 (2011).

70. *See* Bracha, *supra* note 50, at 450-60.

genius."[71] Those who favored broad patent claims were compelled to deny that such a "general claim, monopolizes the law, property or quality of matter which [the inventor] has applied . . . His patent leaves the law, property, or quality of matter, precisely where it found it, as common property, to be used by any one."[72]

The unpatentability of *laws* of nature has thus been—and continues to be[73]—based significantly on considerations of patent scope. However, relating the traditional prohibition to *products* of nature is problematic. Patenting a natural law represents a high level of abstraction and presents the potential for wide preemption of future uses, in a way that patenting a particular piece of biological material might not. As Judge Lourie of the Federal Circuit put it in *Association for Molecular Pathology*, "[a] composition of matter is not a law of nature . . . Any preemption thus is limited."[74] To understand the scope of patentability for natural products, then, we must look elsewhere.

B. *The Murky Origins of the Product-of-Nature Doctrine*

Descriptions of the prohibition on 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. In addition, the one canonical early authority that seems most on point was not nearly as influential or representative as has since been suggested. In the nineteenth century at least, there was very little by way of articulated law on this question.

For example, the product-of-nature doctrine is sometimes traced to the 1874 case of *American Wood-Paper Co. v. Fibre Disintegrating Co*.[75] This is an unfortunate instance of miscasting. In *American Wood-Paper*, the U.S. Supreme Court considered a claim for chemically-treated wood pulp

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71. Smith v. Downing, 22 F. Cas. 511, 519 (C.C.D. Mass. 1850).

72. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS 15 (2d ed. 1854).

73. *See* Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289, 1301 (2012) (citation omitted) ("[E]ven though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are 'the basic tools of scientific and technological work.' And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them . . . or otherwise forecloses more future invention than the underlying discovery could reasonably justify."). *See also* Mark Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011).

74. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1331 (Fed. Cir. 2012).

75. 90 U.S. 566 (1874). *See e.g.*, Linda J. Demaine & 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*.").

(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.[76] 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.[77] The patent was invalid because of the man-made prior art, rather than from anything to do with the natural existence of cellulose in wood.[78]

The next canonical decision in the supposed product-of-nature line is *Cochrane v. Badische Anilin & Soda Fabrik* (BASF).[79] Here, the notion of an operative product-of-nature prohibition 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, the defendant argued to the Supreme Court, *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."[80] 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.

The Supreme Court, however, largely disregarded the product-of-nature argument. Justice Blatchford's opinion focused on the defendant's non-infringement, finding it "so clear that the defendants are not shown to have infringed that we have not deemed it necessary to consider other questions any

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76. *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, 947 (2011) ("Historically, purified natural products were not always patentable").

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

78. Note, however, that the circuit court opinion below included language that came close to a product-of-nature argument. *See* American Wood-Paper Co. v. Fibre Disintegrating Co., 1 F. Cas. 728, 729 (C.C.E.D.N.Y. 1868) ("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 . . . left in a state 'nearly pure,' and consequently fit for the manufacture of paper."). The Supreme Court nowhere endorsed this position.

79. Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884).

80. *Id.* at 297.

further."[81] Blatchford thus hovered on the cusp of dicta when he briefly noted "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."[82] 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 an old product derived from a new source or process could not be patented as though it were a new and distinct product 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."[83] The invention was a high-profile one: cotton farmers across the South were then embroiled in a "Great Jute Boycott" against the Jute Trust, which controlled the bagging of cotton; Latimer's pine fiber offered an alternative to jute bagging material and was thus, as the opinion noted, "unquestionably very valuable."[84] Commissioner Benton J. Hall (an Iowa lawyer-politician with no obvious stake in the Jute Boycott) acknowledged the political sensitivities of the invention by openly declaring his "anxiety, if possible, to secure to the applicant a patent."[85] 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."[86]

Ex parte Latimer cited no direct authority for its conclusion.[87] Instead, Commissioner Hall pointed to the lack of human alteration of the extracted

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81. *Id*. at 309-312.

82. *Id*. at 311.

83. *Ex parte* Latimer, 1889 DEC. COMM'R PAT at 123.

84. *Id.* at 127. *See also To Fight the Jute Trust*, N. Y. TIMES, Apr. 4, 1889; *The Story of an Industry. How Pine Bagging Came to Be Brought into Use*, N. Y. TIMES, May 26, 1889; MICHAEL SCHWARTZ, RADICAL PROTEST AND SOCIAL STRUCTURE: THE SOUTHERN FARMERS' ALLIANCE AND COTTON TENANCY, 1880-1890, at 235-46 (1988).

85. *Ex parte* Latimer, 1889 DEC. COMM'R PAT at 127.

86. *Id.*

87. 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.

fiber, which had not been "in any manner affected or produced by the process, or . . . in any wise been affected, changed, or altered."[88] 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*.[89] 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."[90]

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."[91] 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*."[92]

Ex parte Latimer was 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.[93] 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, Massachusetts received a patent for clam juice that was merely extracted from the clam, filtered, and boiled.[94] Patents subsequently issued for such products as resin extracted from vanilla beans[95] and the isolated perfume of the orris

88. *Id.* at 125.

89. *Id.*

90. *Id.*

91. *Id.* at 125-26.

92. *Id.* at 126.

93. *C.f.* Demaine & Fellmeth, *supra* note 75, 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 . . .").

94. Clam Extract, U.S. Patent No. 395,199 (filed Nov. 12, 1888) (issued Dec. 25, 1888).

95. Oleoresin of Vanilla, U.S. Patent No. 931,805 (issued Aug. 24, 1909) (describing

root.[96] 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."[97] 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.[98]

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 of the day, although these discussed patentable subject matter at length.[99] No reported court decisions cited *Latimer* in the nineteenth century or the first seven decades of the twentieth. This absence cannot be explained by a complete lack of litigation arising on the relevant point of law:[100] the case of *Parke-Davis v. Mulford*, for one, casts some doubt on that proposition, and the 1920s, 1930s, and 1940s saw a number of decisions that rejected patents on explicit product-

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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").

96. Process for Making Ketone from Orris-Root, U.S. Patent No. 559,638 (issued 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 "[w]hile extract of orris-root has heretofore been used, the aromatic principle has to my knowledge never been separated and used in its isolated condition").

97. Product from Thyroid Glands and Process for Making Same, U.S. Patent No. 616,501 (issued Dec. 27, 1898).

98. 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.

99. *See, e.g.*, WILLIAM C. 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 only in digests of Patent Office opinions and rules: *see, e.g.*, 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, at 244 (1898) (where it was the only case listed under heading "Products of Nature"); 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). The exception is *Latimer*'s appearance in a single 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).

100. 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 (3d Cir. 1919).

of-nature grounds. They do not mention *Latimer* either.[101]

The point of this discussion is not to prove that products of nature were regularly deemed patentable: only a truly systematic search of issued patents could properly establish that. It seems more likely that any product-of-nature prohibition 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 and inventiveness. At any rate, it seems as though the now-vaunted decision in *Ex parte Latimer* may have had limited purchase at the time. As of the early twentieth century, neither judicial precedent nor Patent Office practice supplied much guidance for the courts.

C. *The Advent of "Useful Difference"*

Nineteenth-century courts did not pronounce on patenting natural products as such. But the early twentieth century saw doctrinal innovations that would ultimately prove influential in the product-of-nature question. The most important of these doctrines was a concept that I will term "useful difference." The idea was that an isolated natural substance could be the subject of a valid patent—that is, would be considered new, inventive, and sufficiently different from the prior art—if the act of isolation rendered it greatly more useful than the product in its natural state. As a mixture of what we would now think of as novelty (§102), utility (§101), and nonobviousness (§103) ideas, "useful difference" is a fine example of the kind of blended reasoning that shaped patentability before the 1952 Patent Act.

The development of the "useful difference" concept had a technological context. It first arose in chemistry, one of the hotbeds of patent law. Chemical firms were among the pioneers of laboratory-based corporate research in the period around 1900. Along with electrical engineering, chemistry was the leading scientifically-oriented industrial sector of the day.[102] As a technological matter, chemical innovation posed particular challenges for patent law. Many products of the new chemical age 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.[103] Courts were thus

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101. *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).

102. *See* ALFRED D. CHANDLER, SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES (2005); DAVID A. HOUNSHELL & JOHN KENLY SMITH, SCIENCE AND CORPORATE STRATEGY: DU PONT R&D, 1902-1980 (1988); DAVID F. NOBLE, AMERICA BY DESIGN: SCIENCE, TECHNOLOGY, AND THE RISE OF CORPORATE CAPITALISM (1979).

103. GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCES INDUSTRIES, PAST, PRESENT, AND FUTURE 107 (2d ed. 2009).

periodically pressed to decide whether an old product produced in a new way could be the subject of a patent.[104] More than anything else, the earlier cases of *American Wood-Paper* and *Cochrane v. BASF* had addressed themselves to this new-process-old-product issue.[105] *Cochrane* was widely believed to have settled the issue against the patentability of old products obtained from new sources or by new means.[106]

Crucially, though, 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.[107] At least one court had consequently concluded that a product merely containing fewer impurities than appeared in the prior art would not be patentable.[108]

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 art lay in the degree of purity.[109] 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."[110] 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."[111] The opinion in *Union*

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104. The relationship between process and product is a recurring issue in the law of chemical product patents. *See, e.g.*, Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1291-95 (Fed. Cir. 2009) (en banc) (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).

105. 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.

106. ROBINSON, *supra* note 99, at vol. I, pp. 274-75; THOMAS, *supra* note 99, at iv.

107. *American Wood-Paper*, 90 U.S. at 594.

108. Blumenthal v. Burrell, 53 F. 105, 107 (2d. Cir. 1892).

109. 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.").

110. *Blumenthal*, 53 F. at 108.

111. Union Carbide Co. v. Am. Carbide Co., 181 F. 104, 106 (2d. Cir. 1910).

Carbide explicitly referenced the real-world value 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."[112] 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."[113]

This reasoning reached its most prominent expression in 1910, in a pharmaceutical case involving the German chemical giant, Bayer.[114] *Kuehmsted v. Farbenfabriken of Elberfeld Co.* tested Bayer's patent for aspirin (acetylsalicylic acid), "the best selling medicine on the market," with sales of two million ounces per year.[115] The popularity of the patented drug led to large-scale smuggling and imitation, which the German company countered through litigation.[116] Chicago pharmaceutical wholesaler Edward A. Kuehmsted was one of the leading aspirin bootleggers and was chosen as the target of Bayer's test case.[117]

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 it caused adverse side effects such as stomach pain. In the search for an improved remedy, acetylsalicylic acid had been produced in impure form, notably by the German chemist Johann Kraut. Kuehmsted's arguments fell on deaf ears. The courts accepted that Kraut's impure substance had been identified by the same chemical formula as aspirin but noted that those impurities had rendered the compound "comparatively useless."[118] In his substantially 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."[119] As a result, even though "the two bodies [were] analytically the same, . . . Hoffmann's recrystallized product [was]

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112. *Id.* at 108.

113. THOMAS, *supra* note 109, at 34.

114. On the role of German chemical firms in the U.S. pharmaceutical industry, see *infra*, Part IV.B.

115. 179 F. 701, 702 (7th Cir. 1910).

116. DIARMUID JEFFREYS, ASPIRIN: THE REMARKABLE STORY OF A WONDER DRUG 91-92 (2005); JANICE RAE MCTAVISH, PAIN AND PROFITS: THE HISTORY OF THE HEADACHE AND ITS REMEDIES IN AMERICA 112-33 (2004).

117. JEFFREYS, *supra* note 116, at 91.

118. Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 F. 887, 890 (C.C.N.D.IL. 1909).

119. *Id.* at 705.

therapeutically different."[120] The greater utility of the purified form made it a patentable invention.

This was a test of "useful difference."[121] An isolated and purified substance had sufficient distinctiveness from the prior art because it possessed new therapeutic and commercial value. The rule of novelty-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), and nonobviousness (use of "objective indicia" such as commercial success in demonstrating the presence of patentable invention).[122]

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 value of the invention in resolving patentability—but was consistent with other patent doctrines at the time. Foremost of these was the notion of the "pioneer patent," which afforded broader scope to breakthrough inventions.[123] 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."[124]

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. 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

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120. *Id*. at 704.

121. Again, this is my terminology. Contemporaries simply referred to the quality in question as "utility," which invites confusion with the independent utility standard known in the law today. Chemical patent law operated with both usages for much of the twentieth century. A 1960 commentary 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, M. H. M., *Utility as a Factor in Chemical Patentability*, 108 U. PA. L. REV. 1037, 1044-45 (1960).

122. *See, e.g.*, Michael S. Greenfield, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1068-69 (1992).

123. *See* Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379 (2012).

124. WILLIAM K. TOWNSEND, TWO CENTURIES' GROWTH OF AMERICAN LAW, 1701-1901, at 406 (Members of the Faculty of the Yale Law School eds. 1901).

was thus ample reason to hope for the protection of the law.

III. SCIENTIFIC INDUSTRY, PATENT CULTURES, AND PATENT LAW IN THE EARLY TWENTIETH CENTURY

If one period provided the hinge in product-of-nature patenting—both as law and as practice—it was the first third of the twentieth century. By the beginning of the 1930s, patents had successfully issued for a range of isolated biological materials, and the courts had elaborated rationales that would later delineate and justify their patentability.

These events did not take place in a world of legal abstraction. Far from it: the circumstances were freighted with contemporary concerns over science, medicine, and political economy. Understanding the evolving doctrine of patentable subject matter requires some attention to each of these contexts.

A. *American Pharmaceuticals and Patent Skepticism*

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 were 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.[125] Eventually the gap between these products' advertised promise and their 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.[126]

In this climate, a new generation of emerging 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.[127] One of the earliest such firms was Parke-Davis, founded in Detroit as a partnership between Hervey Coke Parke and George S. Davis. After incorporating in 1875, Parke-Davis was

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125. 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 142-53 (1995).

126. SAMUEL HOPKINS ADAMS, THE GREAT AMERICAN FRAUD (1906); YOUNG, *supra* note 126, at chapters 13, 14; Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WISC. L. REV. 329, 340-55 (2011)

127. JONATHAN LIEBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY 4 (1987).

soon joined in the drug manufacturing business by a group of companies that included Eli Lilly, G.D. Searle, and Abbott Laboratories.[128] The H. K. Mulford Company was a later arrival: a prosperous Philadelphia pharmacy that turned to manufacturing in 1891, licensed newly-developed tablet-making machinery, and quickly joined the front rank of pharmaceutical suppliers.[129] As the century drew to a close, these "ethical" companies undertook to become self-consciously 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.[130] During the late 1890s, the two firms competed for the title of "most advanced scientifically."[131]

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.[132] New scientific products were emerging, however. First, research in industrial chemistry began to spin off medical applications. German chemists working with the materials of the 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).[133] British and American experimenters focused more on biological research and on the extraction and purification of natural substances.[134] Research into the glandular products that would soon be known as hormones met with promising results in the mid-1890s.[135] 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

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

129. LIEBENAU, *supra* note 128, at 57-58.

130. *Id.* at 8-9.

131. *Id.* at 34.

132. *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, Guaiac, Lappa, Lithium citrate, Phytolacca root, Potassium iodide, Strychnine, Sulphides."

133. DUTFIELD, *supra* note 103, at 15-17, 83-84.

134. *Id.* at 85-86; Swanson, *supra* note 127, 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.

135. DUTFIELD, *supra* note 103, at 104-8. Hormones were given that name by the English scientist Ernest Henry Starling in 1905.

authorities, this antitoxin also became the first real bulk-manufacturing mainstay of the "ethical" drug companies, Parke-Davis and Mulford included.[136]

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 take out patents, but the profession's official disapproval of patents was repeatedly reaffirmed.[137]

Pharmaceutical companies took varying approaches in response. H. K. Mulford went furthest to accommodate the anti-patent norm. In 1900 the firm adopted the "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."[138] Parke-Davis & Co. 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 selling patented products in the 1890s.[139] 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.[140]

B. *Synthetic Drugs and the German Invasion*

One group did patent drugs in the United States: the Germans. The late-nineteenth-century revolution in scientific drug-making was primarily a German achievement, led by that country's world-leading universities and pioneering corporate researchers in the chemical industry.[141] The synthetic pharmaceutical sector essentially began as a spin-off from dyestuff production, which was the major industrial application of chemistry. Phenacetin, the leading antipyretic, was developed by scientists at Bayer AG from the waste products of coal-tar dyes. Aspirin, whose active ingredient had been previously discovered in willow bark, did not become an effective medicinal substance

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136. LIEBENAU, *supra* note 128, at 48-51.

137. Swanson, *supra* note 127, at 366-68.

138. LIEBENAU, *supra* note 128, at 64.

139. Joseph M. Gabriel, *A Thing Patented is a Thing Divulged: Francis E. Stewart, George S. Davis, and the Legitimization of Intellectual Property Rights in Pharmaceutical Manufacturing, 1879-1911*, 64 J. HIST. OF MED. & ALLIED SCI. 135, 160 (2009).

140. LIEBENAU, *supra* note 128, at 8 (arguing that patent-based strategies did not become central to the U.S. pharmaceutical industry until after the First World War).

141. *See* JOHANN PETER MURMANN, KNOWLEDGE AND COMPETITIVE ADVANTAGE: THE COEVOLUTION OF FIRMS, TECHNOLOGY, AND NATIONAL INSTITUTIONS (2003).

until synthesized from coal tar by Bayer scientists in 1897.[142]

Having emerged within the industrial chemical sector, German synthetic drug makers quickly adopted that industry's intensive and sophisticated patenting behavior, both at home and abroad. German chemical companies delighted in the use of American and British patent laws to leverage their formidable lead in laboratory-based research and development. German firms like BASF, Hoechst, AGFA, and Bayer sought patents 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.[143]

On a far smaller scale (simply because the market was far smaller), the same pattern was echoed in pharmaceuticals. Bayer held the American patents on phenacetin and aspirin, both of which were enforced against all comers through Bayer's U.S. agent, the Farbenfabriken of Elberfeld Company.[144] 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 for distribution by public-health authorities, the appearance of this patent briefly threw the industry into panic. American firms vowed unified resistance, and commentators promised Behring "a harvest of shame and not the harvest of American dollars that he expected."[145] Both the Parke-Davis and Mulford companies publicly "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."[146] Perhaps due to this determined opposition, Behring's assignee Hoechst AG did not enforce the patent.[147]

German patenting lent the whole question of drug patents in the United States a protectionist edge. Some of the most direct public-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.[148] The retail druggists'

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142. DUTFIELD, *supra* note 103, at 14-18.

143. JONATHAN LIEBENAU, THE CHALLENGE OF NEW TECHNOLOGY: INNOVATION IN BRITISH BUSINESS SINCE 1850 (1988); MURMANN, *supra* note 142, at 40.

144. DUTFIELD, *supra* note 103, at 16-18.

145. *See, e.g.*, *The Antitoxin Patent of Behring*, 12 AMERICAN MEDICO-SURGICAL BULLETIN 847 (1898).

146. *Id.*

147. DEREK S. LINTON, EMIL VON BEHRING: INFECTIOUS DISEASE, IMMUNOLOGY, SERUM THERAPY 239 (2005).

148. *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,*

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.[149]

Despite these attempts to clear the field of product patents—or perhaps because of their failure—the eventual lesson learned by American firms was not to reject German scientific methods or patenting, but to imitate them. In retrospect, the history of medicine, business, and patents during this period echoes the story of the later gene patenting era. 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. But 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.

IV. THE ADRENALIN PATENT

The patenting of adrenalin—and subsequent litigation over that patent—was a key episode in the changing culture of American life science patenting. It later emerged as a seminal moment in the law of product-of-nature patenting as well. For a long time, the history of these events has not been well understood.[150] For our purposes, that history illustrates three things. The process by which the adrenalin patent was obtained shows how "product of nature" issues were handled in the Patent Office, and notably how the limits of *Ex parte Latimer* were navigated. The litigation over adrenalin reveals the legal theory that settled patentability: not a judicial innovation as such, but the

Medicines, and Medical Compounds, 58th Cong. (1904) [hereinafter "1904 Hearings"]; Swanson, *supra* note 127, at 370.

149. 1904 Hearings, *supra* note 149, 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.

150. Jon Harkness, *Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in* Parke-Davis v. Mulford, 93 J. PAT. & TRADEMARK OFF. SOC'Y 363 (2011) (providing another recent historical treatment). I differ with Harkness's views in a number of respects, as will become clear.

application of the "useful difference" concept that had developed in chemical patent law. Finally, the aftermath of the *Parke-Davis* case shows that both the law and practice of natural-product patenting bore the mark of Learned Hand's decision.

A. *Patenting Adrenalin*

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 medical and surgical use spurred an immediate search for the active substance—or what chemists then called the active "principle."[151] 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 active 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.[152] Meanwhile the Austrian chemist Otto von Fürth isolated a similar compound, which he called "suprarenin."[153] 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.[154] 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.[155] 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 used in distilling.[156] Between 1889 and

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151. E. M. Tansey, *What's in a Name? Henry Dale and Adrenaline, 1906*, 39 MED. HIST. 459, 464-65 (1995).

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

153. Tansey, *supra* note 152, at 465.

154. 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 155 (2005) (marketing of Fürth's suprarenin by Hoechst).

155. Horace W. Davenport, *Epinephrin(e)*, 25 PHYSIOLOGIST 76, 78 (1982).

156. DAVID L. COWEN, 21 AMERICAN NATIONAL BIOGRAPHY 265-66 (John A. Garraty

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.[157] "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.[158] Sometime 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.[159] With this step, Takamine had succeeded in isolating the first ostensibly pure hormone.[160] He called it "Adrenalin."

Takamine filed for a patent on his invention in November 1900. It is quite likely that this was of 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.[161] 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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and Mark C. Carnes eds., 1999); Davenport, *supra* note 156, at 78-79.

157. Davenport, *supra* note 155, at 79.

158. Deposition of Frank G. Ryan, Apr. 5, 1910, Transcript of Record at 309-10, Parke-Davis & Co. v. H. K. Mulford Co., 196 F. 496 (2d Cir. 1912) (No. 4363) (on file at the National Archives and Records Administration at New York Region, New York City, Box 1684, RG276) [hereinafter "Transcript of Record"] (Ryan's testimony describes Takamine as "a chemist in the employ" of the company, but I have not been able to corroborate this description). *See also* Davenport, *supra* note 156, at 79 (noting that E. M. Houghton, Director of Parke-Davis' Research Laboratory, performed physiological tests for Takamine).

159. Davenport, *supra* note 156, at 79.

160. Takamine's extract later turned out to contain two hormones, adrenaline and noradrenaline (or epinephrine and norepinephrine). *See* PARASCANDOLA, supra note 153, at 58.

161. 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. *See* Naomi R. Lamoreaux and Kenneth L. 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 28-40 (Naomi Lamoreaux et al. eds., 1999). 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, Takamine faced legal obstacles in gaining his patent. 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 "[t]he product, Adrenalin, consisting of the active principle of the Suprarenal Glands, in a white, solid, crystalline form."[162] Patent Office examiner James Littlewood, an experienced member of the Office's Division of Chemistry, immediately rejected the claim as "drawn to a product of nature, merely isolated by applicant, and hence . . . not drawn to such patentable subject matter as required by statute."[163] Littlewood cited *Ex parte Latimer* and *Cochrane v. BASF* as authority without further elaboration. Knight Bros. may have been surprised by rejection on these grounds: 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."[164] The examiner reaffirmed the rejection, adding a citation to the *Wood-Paper Patent Case*.[165]

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."[166] Latimer's 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.[167] By contrast, Takamine's active principle had never existed as a white, crystalline substance, and its "complete transformation" rendered it "therefore new."[168] 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 nature; neither did Latimer's fibre, but it did exist and therefore is not patentable."[169]

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162. Jokichi Takamine, Patent Application for "Glandular Extractive Products," Nov. 5, 1900, Transcript of Record, *supra* note 158, at 872.

163. Communication from Examiner, Dec. 7, 1900, Transcript of Record, *supra* note 158, 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.*

164. Jokichi Takamine, Amendment, Oct. 22, 1901, Transcript of Record, *supra* note 158, at 883.

165. Communication from Examiner, Nov. 7, 1901, Transcript of Record, *supra* note 158, at 884.

166. Jokichi Takamine, Amendment, Sept. 25, 1902, Transcript of Record, *supra* note 158, at 887 (quoting *Ex parte* Latimer).

167. *Id.* at 888.

168. *Id.* at 889.

169. Communication from Examiner, Oct. 17, 1902, Transcript of Record, *supra* note

Thus foiled, Takamine changed course. In a new patent application containing sixteen product claims,[170] 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."[171] 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.

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."[172] "Applicant is the first to produce a substance which is stable and does not deteriorate nor decompose on keeping," they noted.[173] Accordingly, key claims specified the product "in a stable and concentrated form, and practically free from inert constituents."[174] 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."[175] These also happened to be precisely the characteristics that made Takamine's adrenalin a significant medical advance.

That was enough. With the patent no longer framed as claiming an extracted active principle, but instead worded to claim a stable, purified, and concentrated compound whose effects tracked those of the adrenal glands, the application was approved and granted in June 1903 as U.S. Patent 730,176.[176] Takamine received a patent (no. 730,175) for his process claims on the same day, and a further patent for a salt of the active principle (no. 753,177) a few

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158, at 890.

170. Process of Obtaining Adrenalin from Suprarenal Glands, U.S. Patent No. 730,175 (filed Nov. 5, 1900) (issued June 2, 1903). 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."

171. Jokichi Takamine, Application of Jan. 14, 1903, Amendment of Mar. 14, 1903, Transcript of Record, *supra* note 158, at 842-44 (explaining 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, Transcript of Record, *supra* note 158, at 851-52.

172. *Id.* at 847 (quoting *Ex parte* Latimer).

173. Jokichi Takamine, Amendment of Mar. 14, 1903, Transcript of Record, *supra* note 158, at 845.

174. *Id.* at 842-44.

175. *Id.* at 846.

176. Glandular Extractive Product, U.S. Patent No. 730,176 (filed Nov. 5, 1900) (issued June 2, 1903).

months later.[177]

B. *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.[178] By 1904, Parke-Davis sold more than $200,000 worth of Adrenalin products. It was the firm's greatest success to date.[179] "As cocaine is to painless surgery," the company boasted, "so Adrenalin [is] to bloodless surgery."[180]

In 1905, however, a number of other firms entered the market, cutting Parke-Davis's sales nearly in half.[181] That same year, the firm commenced litigation under the Takamine 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.[182] Parke-Davis chose to sue under its two product patents 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"— something the company "did not wish to do if it can be avoided."[183] Given that H. K. Mulford continued to trumpet its high-minded stance against drug product patents in general,[184] it may have seemed wise for Parke-Davis to invoke the looming specter of German competition as a justification for wielding them.

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177. Process of Obtaining Adrenalin from Suprarenal Glands, U.S. Patent No. 730,175 (filed Nov. 5, 1900); Glandular Extractive Compound, U.S. Patent No. 753,177 (filed May 12, 1903).

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

179. Frank G. Ryan Dep., Transcript of Record, *supra* note 158, at 310-12.

180. Brief for Defendant-Appellant, Parke-Davis & Co. v. H. K. Mulford Co., 196 F. 496 (2d Cir. 1911) (No. 4363) (on file at the National Archives and Records Administration at New York Region, New York City, Box 1684, RG276) [hereinafter "Brief of Parke-Davis"].

181. Transcript of Record, *supra* note 158, at 310. Companies offering rival products included Armour & Co. (Suprarenalin), Eli Lilly (Sanguestine), H.K. Mulford (Adrin), and others. *The Suprarenal War,* 16 PRACTICAL DRUGGIST AND REVIEW OF REVIEWS 328, 328 (Aug. 1904).

182. 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., Vo. S, RG21 (on file at the National Archives and Records Administration at New York Region, New York City) [hereinafter "Equity Docket"].

183. Brief of Parke-Davis, *supra* note 181, at 3.

184. *See supra* note 139 and accompanying text.

The parties spent fully five years gathering evidence and testimony in the case. Attorneys for both sides were major figures of the patent bar.[185] Both they and the principal expert witnesses were repeat players in such cases; notably, the lead attorney and the main expert for Parke-Davis had performed the same role for Bayer in the *Kuehmsted* aspirin litigation. The bulky record of proceedings was devoted mostly to the depositions of Charles F. Chandler, an eminent New York professor of chemistry and pharmacy, who testified for Parke-Davis & Co., and Samuel P. Sadtler, a longtime professor of organic and industrial chemistry at the University of Pennsylvania, who testified for Mulford.[186] 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."[187] In years to come, he would be known, among other things, as a great authority in patent law.[188] In early 1911 though, he was a relative novice on the bench, newly escaped from a disappointingly tepid career as a Wall Street lawyer.[189] By becoming a federal judge of the Southern District of New York, Hand had certainly put himself on the front line of American patent law. The Circuit Court[190] 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, or roughly twenty percent

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185. 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.

186. Depositions of Chandler and Sadtler, Transcript of Record, *supra* note 158, at 17, 404. 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. *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).

187. 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)).

188. *See, e.g.*, GERALD GUNTHER, LEARNED HAND: THE MAN AND THE JUDGE 256, 258-59, 313 (1994); Stephen H. Philbin, *Judge Learned Hand and the Law of Patents and Copyrights*, 60 HARV. L. REV. 394 (1947).

189. On Judge Hand's career at the bar, see GUNTHER, *supra* note 189.

190. 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).

of all civil suits commenced there.[191] 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.[192] 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."[193]

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. 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. "[A]ll of [the] four alleged anticipating products never existed except in the form of a salt," Hand reasoned, while Takamine's claims were drawn only to the alkaline base of the active principle and were "especially designed to exclude a salt."[194] Takamine was thus not anticipated.

Hand treated all other invalidity arguments—including the product-of-nature argument—as "technical objections" to the patent.[195] His response included the language that 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.'"[196] Hand answered, in the first instance, that Takamine had been the first to isolate from the adrenal gland "a

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191. 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 (on file at the National Archives and Records Administration at New York Region, New York City). In the fiscal year 1910, 1,457 civil suits were commenced in the District and Circuit Courts of the district. *See* Att'y Gen. Ann. Rep. 149 (June 30, 1910).

192. 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 at* http://oasis.lib.harvard.edu/oasis/deliver/~law00059.

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

194. 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.

195. *Id.* at 102-03. The other notable "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."

196. *Id.* at 103.

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."[197] Famously, 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*.[198]

Of these statements, the last was the key. Hand left no doubt that his reasoning followed the pragmatic, inventor-rewarding rationale of recent cases such as *Kuehmsted*, the aspirin decision. "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 "[w]hatever 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 speak, from such facts . . . . [T]his 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.[199]

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."[200] 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

197. *Id*.
198. *Id*. (emphasis added).
199. *Id.* at 114-15.
200. *Id.* at 115.

authoritative scientific assistance in the administration of justice, no one knows."[201]

C. *Was* Parke-Davis *Rightly Decided?*

The two sides of the gene patenting debate differ over whether *Parke-Davis* was rightly decided.[202] At trial in *Association for Molecular Pathology*, counsel for the patent challengers branded Hand's decision "erroneous" for two reasons. First, because it conflicted with the Supreme Court's holdings in *American Wood-Paper* and *Cochrane v. BASF*.[203] Second, the challengers 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.[204]

This second argument—call it the "nature is different" theory—falls flat. As discussed above,[205] 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.

Consistency with prior law is different matter. Jon Harkness, a scholar of medical history and law, has recently argued that the "greatest shortcoming" of Hand's Parke-Davis opinion was "his failure to take *Ex parte Latimer* into account."[206] Harkness puts this down to a failure of knowledge on the part of the "inexperienced and under-informed" Judge Hand.[207] He also attributes the PTO's eventual acceptance of the Takamine patent, after initial rejection under

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201. *Id*.

202. *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 at 3, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, F. Supp. 2d 181 (2010) (No. 09 Civ. 4515) [hereinafter "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.'").

203. Plaintiffs' Memorandum, *supra* note 14, at 24-25. 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. *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).

204. Plaintiffs' Memorandum, *supra* note 14, at 25; Gipstein, *supra* note 204, at 23.

205. *See infra*, Part III.B.

206. Harkness, *supra* note 151, at 391.

207. *Id.* at 399.

Latimer, to the gradual "wearing down" of the examiner.[208] On the strength of *Latimer*'s absence from the *Parke-Davis* deliberations, Harkness concludes that *Parke-Davis* was not a case where "the patentability of an isolated or purified product of nature" was at issue.[209]

I disagree. *Parke-Davis* was a case about "the patentability of an isolated or purified product of nature" because it did, in fact, concern a patent for an isolated and purified product of nature. The fact that the case was not argued in terms of a "product of nature" doctrine says more about the lack of a clear doctrine than it does about the issues at stake. What happened at the Patent Office resulted from the limited scope of *Ex parte Latimer*, which prevented the examiner from allowing a "product . . . simply separated from impurities," but fell away as an objection once Takamine redrafted his claims to emphasize the new character of his purified adrenal extract and the new utility allowed as a result.[210] To say that the product-of-nature prohibition was so readily drafted around is also to say that it was not much of a prohibition.

It is true that *Latimer* did not figure in the *Parke-Davis* trial (either in the briefing or the decision) and thus that the litigation cannot be considered as a direct referendum on the *Latimer* rule. But that should be a clue to us: not that the parties and the court misunderstood what was going on in the case,[211] but that American law at that point lacked a robust product-of-nature category, distinct from questions of novelty, utility, and inventiveness. Modern skeptics of *Parke-Davis* are left arguing that Hand should have *sua sponte* invoked the Commissioner of Patents' decision in *Ex parte Latimer*—not only giving that opinion its first judicial recognition, but also extending its holding to substances that had been purified as well as extracted, and which possessed new utilities and functions not found in nature.[212] However, nothing required Hand to do so, and nobody asked.

The remaining question is whether *Parke-Davis* conformed to the Supreme Court's earlier rulings, *American Wood-Paper* and *Cochrane v. BASF*. Neither was a product-of-nature holding *per se*, but each suggested a rule that might bear on naturally-derived products 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.[213] Applying these decisions to products derived from nature essentially meant treating the nature problem as a

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208. *Id.* at 391.

209. *Id.* at 399.

210. *See infra*, Part V.A.

211. For one thing, the lawyers on each side were two of the leading patent lights of the patent bar.

212. *See infra* notes 95-101 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.

213. *See infra* notes 76-83 and accompanying text.

subset of the novelty inquiry: the claimed product could not be patented *if* it was in the prior art.[214] Crucially, though, neither opinion decided where on the spectrum of changes to the prior art one should draw the line of patentable novelty. The Court in *American Wood-Paper* had "doubted" that a "slight difference" in purity could constitute a new product,[215] but that mild statement left ample room for greater degrees of purification to confer patentability. *Cochrane* indicated that a synthetic product identical to the prior art substance could not be patented,[216] 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,"[217] 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."[218] Most bizarrely, the assertion conflicted with the central reasoning 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,[219] 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, as we shall see, has sometimes been taken as such. Loose language on the part of the author bears significant responsibility for this state of affairs. If he were now around to object, Learned Hand would mostly have himself to blame.

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214. 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. 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.

215. American Wood-Paper, 90 U.S. at 594.

216. Cochrane, 111 U.S. at 311.

217. Parke-Davis, 189 F. at 103 (emphasis added).

218. Parke-Davis, 189 F. at 103.

219. *See, e.g.*, Utility Examination Guidelines, *supra* note 7, at 1093.

V. THE PRACTICE AND LAW OF PATENTING NATURE AFTER *PARKE-DAVIS*

The adrenalin case had two distinct legacies in American patent law. One was doctrinal: Learned Hand's *Parke-Davis* decision eventually became a major—though sometimes misunderstood—precedent in the law of patentability. The other was practical: the adrenalin patent marked the beginning of changes in the practices of natural-product and pharmaceutical patenting. Given courts' inclination to look at historical patent practice as an indicator of settled law, there is a kind of legal authority in this story too.

A. *Practice*

Parke-Davis has been treated by some as representative evidence that the United States has "long and unhesitatingly granted patent protection" to similar substances.[220] As Judge Moore put it in *Myriad*, "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,* and the Patent Office's longstanding policy and practice," including "a century-long history of affirming patent protection for isolated and purified biological products."[221] On the other side, *Parke-Davis* has been readily branded as a historical outlier or an error.[222]

The truth is more interesting than either of these accounts. The adrenalin battle reveals changes in the culture and practices of life-science patenting—changes of which adrenalin was both an example and a catalyst. Researchers, firms, and their lawyers learned the lessons of the Takamine patent, which in turn set a model for the next generation of patents on isolated naturally-occurring products.

Takamine's adrenalin patent reflected a world in which principled resistance to biomedical product patenting was crumbling. In the shadow of the *Kuehmsted* and *Parke-Davis* cases, the distance between "ethical" pharmaceuticals and patented medicines finally dissolved. The courts observed no distinction, referring, for example, to patented aspirin as an "ethical remedy" in the *Kuehmsted* case.[223] At the same time, the organized medical profession softened its stance. In 1909, the American Medical Association convened a Committee on Patents and Trade-Marks, which recommended that the body dispense with its opposition to product patents. Such grants were now sufficiently established, the group found, that abolishing them would be "impractical."[224] During the first decade of the twentieth century, much of the

220. *In re* Bergy, 596 F.2d at 975.
221. *Ass'n for Molecular Pathology II*, 689 F. 3d. at 1344, 1347.
222. *See, e.g.*, Demaine & Fellmeth, *supra* note 75, at 339-45.
223. *Kuehmsted*, 179 F. at 702.
224. Gabriel, *supra* note 140, at 171.

medical profession had accepted the basic legitimacy of drug patents.[225]

The reconciliation of pharmaceutical manufacturers to product patents was even more complete and more directly traceable to the adrenalin case. H.K. Mulford, the most outspoken of the holdouts, 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."[226] The year after Hand's decision though, Mulford abandoned its pledge and began to seek product patents.[227] Not every protagonist in the adrenalin litigation had the same response. John J. Abel, the pioneering academic pharmacologist whose claim to the discovery of adrenalin lost out to Takamine's patent, emerged from the litigation with a pronounced suspicion of commercialized science, and founded the American Society for Pharmacology with an explicit stance against drug patenting.[228] Abel's views were increasingly overtaken though, even within the academic community.

What followed in the 1910s and 1920s was a procession of hormone discoveries, on which the adrenalin patent left a clear mark. In 1916, the biochemist Edward Kendall, who had worked at Parke-Davis in 1910-1911, applied for a patent on thyroxin. Kendall's product claims closely tracked the language of Takamine's: rather than claiming the hormone as such, they covered a "product, obtained from thyroid tissue, practically free from inert gland tissue," and functionally defined in terms of its "physiological properties of producing tachycardia."[229]

The most important deployment of the Takamine format was insulin, the next great discovery of the "hormone era."[230] Insulin in isolated and purified form was first used to treat diabetes by scientists and physicians at the University of Toronto in 1922. Conscious of the value of their breakthrough and wanting to direct and regulate the development of an effective but potentially dangerous treatment, the Toronto team decided to seek a patent for

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225. *Id.* at 171.

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

227. Liebenau, *supra* note 128, at 64.

228. The Society excluded industrial chemists at its founding in 1908, and pointedly joined the American Medical Association's opposition to drug patenting. PARASCANDOLA, *supra* note 153, at 115.

229. Thyroid Product and Process of Preparing the Same, U.S. Patent No. 1,392,767 (issued Oct. 4, 1921). Compare, for example, claim 1 of Takamine's patent: "A substance possessing the herein-described physiological characteristics and reactions of the adrenal glands in a stable and concentrated form, and practically free from inert and associated gland tissue."

230. *See* Dutfield, *supra* note 103, at Chapter 5.

their compound.[231] J. J. R. Macleod, the director of the university's physiological laboratory, identified Takamine's adrenalin and Kendall's thyroxin patents as the primary precedents for such a step. Macleod also sought out advice directly from Kendall, then at the Mayo Clinic, and from lawyers at the Eli Lilly pharmaceutical company.[232] Based on these sources, the Toronto researchers produced a patent essentially following Takamine's 1903 claim language. The patent described the "hormone in practically pure form," with product claims covering a "concentrated form" of the glandular insulin extract "practically free from inert and associated gland tissue and injurious substances" and defined by its blood-sugar decreasing effect.[233] Insulin was neither the first hormone to be patented after adrenalin nor the first such patent to use Takamine-style claims,[234] but it emphatically placed a landmark breakthrough in biological science under the aegis of the patent system. Two members of the Toronto team shared the Nobel Prize for medicine in the year that the patent issued.[235]

The final piece of the puzzle was university management of hormone patents. The practice was pioneered by the University of California professor T. Brailsford Robertson, who assigned rights to his pituitary extract to the University.[236] Edward Kendall, of the Mayo Clinic, took a further step by assigning his thyroxin rights to the University of Minnesota, on the condition that it organize the commercial exploitation of the drug in the interests of the medical profession.[237] The University licensed production to the Squibb pharmaceutical firm but used its license to control production quality and the final price of the product. Toronto followed a similar arrangement, establishing an Insulin Committee to regulate the quality and price of insulin and issuing non-exclusive licenses to pharmaceutical manufacturers.[238]

University patent management cemented two trends. One was academic scientists' growing willingness to patent important biological discoveries.

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231. Maurice Cassier & Christine Sinding, *Patenting in the Public Interest: Administration of Insulin Patents by the University of Toronto*, 24 HIST. & TECH. 153, 153-54 (2008).

232. Cassier & Sinding, *supra* note 232, at 154-58.

233. Extract Obtainable from the Mammalian Pancreas or from the Related Glands in Fishes, Useful in the Treatment of Diabetes Mellitus, and a Method of Preparing It, U.S. Patent No. 1,469,994 (issued Oct. 9, 1923).

234. The earliest I have found to do so is Extractive Product from the Hypophysis Gland, U.S. Patent No. 1,296,063 (filed Sept. 25, 1912) (issued March 4, 1919).

235. Dutfield, *supra* note 103, at 113-14.

236. T. Brailsford Robertson, *The Utilization of Patents for the Promotion of Research*, 46 SCIENCE 371 (1917). *See also* Swanson, *supra* note 127, at 379.

237. Cassier & Sinding, *supra* note 232, at 155. An attempted assignment of the patent to the American Medical Association "foundered due to lack of agreement among the AMA membership about whether medical patents should be allowed at all." Swanson, *supra* note 127, at 373.

238. Cassier & Sinding, *supra* note 232, at 155.

University research came to include not only hormones but also vitamins, the next clutch of arguably-natural products to receive patent protection.[239] The other trend was legal acceptance of the hormone patents themselves—a process that was confirmed by judicial silence as much as anything else. When the Toronto researchers sought their patent for insulin, questions were raised about its validity, including on product-of-nature grounds.[240] No legal challenge emerged, however, thanks to the University's policy of granting non-exclusive licenses to multiple pharmaceutical manufacturers. In the absence of patent-based competition, Eli Lilly's scientific director could reassure the patentees that American pharmaceutical companies had "too much at stake themselves to care to provoke a fight of this nature."[241] By the beginning of the 1930s, hormone patents were sufficiently conventional at the Patent Office that they simply claimed "the hormone," rather than using the circumspect and functional claiming of earlier decades.[242] As a matter of practice, Takamine and his imitators had established a space for patents covering isolated biological material.

B. *Law*

As a matter of black-letter law, however, natural-product patents encountered a much clearer set of prohibitions in the 1920s, 1930s, and 1940s. During these years, the political and judicial climate turned sharply against patents.[243] Progressive-Era and New Deal suspicion of corporate monopoly began to produce greater restrictions on business uses of patent rights. Around the turn of the century, courts had rebuffed challenges to anticompetitive patent strategies with statements like, "Within his domain, the patentee is czar. The people must take the invention on the terms he dictates."[244] Two decades later, the treatment of practices such as patent pooling, tying, cartelization, and other restrictive licensing was moving from "approval" and "indifference" to "disapproval" and "strict interpretation."[245] The Antitrust Division of the

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239. One of the largest university patent management institutions, the Wisconsin Alumni Research Fund, began with a process patent for vitamin D preparation. *See* Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Fund*, 80 ISIS 375 (1989). The University of Pittsburgh professor Charles G. King attempted to patent isolated vitamin C, but was denied because of anticipation by an earlier researcher:. In re King, 107 F.2d 618 (C.C.P.A. 1939).

240. Cassier & Sinding, *supra* note 232, 157-58.

241. Letter quoted in Cassier & Sinding, *supra* note 232, at 168, n.34.

242. *See, e.g.*, Hormone and Process of Obtaining the Same, U.S. Patent No. 1,967,350 (filed Mar. 3, 1930) (issued Jul. 24, 1934 to Edward A. Doisy) (claiming "the isolated ovarian follicular hormone").

243. Steven Wilf, *The Making of the Post-War Paradigm in American Intellectual Property Law*, 31 COLUM. J. L. & ARTS 139, 191-202 (2008).

244. Victor Talking Mach. Co. v. Fair, 123 F. 424, 426 (7th Cir. 1903).

245. FLOYD L. VAUGHAN, THE UNITED STATES PATENT SYSTEM: LEGAL AND ECONOMIC

Department of Justice conducted aggressive litigation throughout the 1920s and 1930s, including a series of pitched battles with corporate giants General Electric, AT&T, and RCA.[246] Governmental skepticism of patent power reached a peak with the Temporary National Economic Committee, a congressional body established in 1938, whose reports described a world of closed "corporate estates" fenced off by thousands of patents.[247]

More diffusely, courts applied greater skepticism to issues of patent validity. U.S. Courts of Appeals upheld 46% of adjudicated patents in 1921-30, 34% in 1931-40, and 22% in 1941-50[248]—an imperfect measure of judicial attitudes,[249] but one that contemporaries took to indicate a growing hostility to patent rights. This was the era of Justice William O. Douglas's notorious pronouncement that patentable invention required nothing less than "the flash of creative genius,"[250] and of Justice Robert Jackson's lament that "the only patent that is valid is one which this Court has not been able to get its hands on."[251]

It was in this context that a new group of product-of-nature decisions emerged. *General Electric Co. v. De Forest Radio Co.*[252] involved GE's Coolidge patent for improved tungsten lamp filaments. The Coolidge patent was one of the three principal patents through which GE controlled 70% of the country's electric lamp business, and which had been the subject of a bitterly-fought antitrust action decided against the government by the Supreme Court in 1926.[253] Among his claims, Coolidge had included one for "[s]ubstantially pure tungsten having ductility and high tensile strength," and others for tungsten and tungsten wire with ductile and pliable qualities.[254] One threshold

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CONFLICTS IN AMERICAN PATENT HISTORY, at vii-xvi (1956).

246. *Id.*, 73-77, 128-29.

247. WALTON HALE HAMILTON, PATENTS AND FREE ENTERPRISE 43 (1941). *See also* Wilf, *supra* note 244, at 200-201 (describing the political context and proposals of the TNEC).

248. Lawrence Baum, *The Federal Courts and Patent Validity: An Analysis of the Record*, 56 J. PAT. OFF. SOC'Y 758, 760 (1974).

249. Jason Rantanen, *Why* Priest-Klein *Cannot Apply to Individual Issues in Patent Cases* (U Iowa Legal Studies, Research Paper No. 12-15, 2012) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2132810 (discussing the literature on patentee win rates in litigation generally and noting that overall litigation outcomes disguise potential variations in win rates—and thus presumably judicial attitudes—on individual issues of patent law).

250. Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941). *See also* John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 41-42 (2007) (describing the use of the inventiveness or nonobviousness requirement to raise the bar for patentability).

251. Jungerson v. Ostby & Barton Co., 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

252. 28 F.2d 641 (3d Cir. 1928).

253. United States v. Gen. Elec. Co., 272 U.S. 476, 481 (1926).

254. Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d at 643.

question in the case was whether Coolidge had claimed a new and artificial form of the metal, as the inventor and others had apparently maintained, or a pure form of natural tungsten.[255] Finding that Coolidge had claimed "the tungsten of nature," the Third Circuit held that "he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element."[256] The court did not cite on-point authority for its premise, but appeared to be following the district court's determination below that the ductility of tungsten was "a discovered, inherent property, not an invented one."[257] *General Electric v. De Forest* soon had consequences for similar claims. The Court of Customs and Patent Appeals followed the Third Circuit in rejecting patent applications for ductile uranium[258] and ductile vanadium,[259] holding that the purity and ductility of the claimed metals were each "a quality of a natural product and as such . . . not patentable."[260]

In the biotechnology context, the outstanding anti-patentability decision of these years was *Funk Brothers Seed Co. v. Kalo Inoculant Co*.,[261] decided by the Supreme Court in 1948. Unlike the metals cases, which are primarily cited now as examples of a longstanding bar on patents for natural products, *Funk Brothers* is one of the two or three leading precedents guiding the *Myriad* courts' rulings, and its reasoning has come in for much scrutiny.[262] The invention in question was an "inoculant package" containing multiple species of bacteria useful in enhancing the nitrogen-fixing activities of crops. Previous inoculants had contained only one species at a time, because otherwise the bacteria inhibited each other when combined. Bond, the inventor of the patent at issue, had discovered certain strains that did not have the mutually inhibitory effect, and had patented the mixed culture.[263] At trial, the district court had "with reluctance" found that Bond had merely discovered a law of nature

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255. *Id.* at 642. Coolidge in his specification announced that his process converted "tungsten bodies . . . from their original crystalline character to a condition having all the characteristics of a ductile metal," thus forming "a new product, viz: wrought tungsten, and, if the process be carried far enough, ductile tungsten, a material having properties and utilities different from those of any previously known substance." Tungsten and Method of Making the Same for Use as Filaments of Electric Lamps and for Other Purposes, U.S. Patent No. 1,082,933 (filed Jun. 19, 1912) (issued Dec. 30, 1913).

256. *Id.* at 642.

257. Gen. Elec. Co. v. De Forest Radio Co., 17 F.2d 90, 96 (D. Del. 1927), *modified*, 28 F.2d 641 (3d Cir. 1928).

258. *In re* Marden, 47 F.2d 957 (C.C.P.A. 1931).

259. *In re* Marden, 47 F.2d 958, 959 (C.C.P.A. 1931).

260. *Id* at 959.

261. 333 U.S. 127 (1948).

262. *See, e.g.*, Risch, *supra* note 32, 599-600; Ted Sichelman, *Funk Forward*, *in* INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP (Rochelle Dreyfuss, Jane Ginsburg & Carol Rose eds., forthcoming 2013), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2035027.

263. 333 U.S. at 129-130.

(meaning the natural non-inhibition of the particular strains), and that his combined product was thus unpatentable.[264] The Seventh Circuit reversed, on the grounds that Bond's true contribution was an "application of scientific knowledge to things existing in nature and the utilization of them in a desirable composite product which had not been previously achieved."[265] The Supreme Court, in an opinion by leading patent skeptic William O. Douglas, reversed again, and invalidated the patent.

The Supreme Court's *Funk Brothers* decision made two moves. The first was to issue a general statement that laws of nature are unpatentable:

> Bond does not create state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[266]

The second step was to deem Bond's particular application of the discovery unpatentable. Despite the commercial usefulness of the mixed culture, the mixture itself fell "short of invention within the meaning of the patent statutes."[267] "[O]nce nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered," Justice Douglas explained, "the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention."[268]

Funk Brothers was a recapitulation of the nineteenth-century law-of-nature cases,[269] with all their attendant dilemmas about where to locate the line between the unpatentable law of nature and its potentially patentable application. Douglas's decision drew the demarcating line by declaring that obvious applications of a law of nature could not be patented, even if the natural phenomenon itself were a new and nonobvious discovery. The addition to the law-of-nature canon thus consisted essentially of updating it with the 1940s Supreme Court's steep inventiveness (i.e. nonobviousness) requirement.

Largely absent from *Funk Brothers* and the preceding metals cases were *Parke-Davis* and the other "useful difference" cases. The patent-owner in *Funk*

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264. Kalo Inoculant Co. v. Funk Bros. Seed Co., 161 F.2d 981, 986 (7th Cir. 1947) (describing the district court's unreported decision).

265. *Id.*

266. *Funk Bros.*, 333 U.S. at 130.

267. *Id.* at 131.

268. *Id.* at 132.

269. *See infra*, Part III.A.

Brothers cited *Parke-Davis* in the course of arguing that the combination was "for every practical purpose a new thing,"[270] but the Court passed over the argument without comment. Nor did the metals cases have anything to say about the useful difference cases, despite their relevance to questions of purity and utility. During those years, *Parke-Davis* was in fact seldom cited for its (now) principal holding. Instead it was best known for Hand's complaints about expert testimony and call for a system of scientific advisors in technical cases.[271] Even as a patent case, *Parke-Davis* was generally cited for Hand's remarks about claim multiplication and the advisability of a patentee drafting claims of various breadths.[272] 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).[273]

All of this changed in 1958, with the Fourth Circuit's decision in *Merck & Co. v. Olin Mathieson Chemical Corp.*[274] The case coincided with the peak of Learned Hand's prestige in the legal profession: three years before the judge's death, and in the same year that he delivered his career-summing Holmes

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270. Brief for Respondent at 57, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (No. 280), 1948 WL 47563 (quoting Parke-Davis, & Co. v. H. K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911)).

271. 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 called 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 judicial process," and quoted Hand in support. Felix Frankfurter, *Hours of Labor and Realism in Constitutional Law*, 29 HARV. L. REV. 353, 372 (1916). 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. *See, e.g.*, Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Found., 402 U.S. 313, 350 (1971); Marconi Wireless T. Co. of Am. v. United States, 320 U.S. 1, 80 (1943); Perkins v. Endicott Johnson Corp., 128 F.2d 208, 216 (2d Cir. 1942); Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court—and Vice Versa*, 59 AM. U. L. REV. 787, 789 (2010); Edward V. Di Lello, *Fighting Fire with Firefighters: A Proposal for Expert Judges at the Trial Level*, 93 COLUM. L. REV. 473, 507 (1993); 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); Note, *The Federal Trade Commission as Special Master in Anti-Trust Suits*, 30 HARV. L. REV. 168, 170 (1916). 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. *See, e.g.*, Watson v. United States, 979 A.2d 1254, 1268 (D.D.C. 2009); Audi Vision Inc. v. RCA Mfg. Co., 136 F.2d 621, 625 (2d Cir. 1942); United States v. St. Pierre, 132 F.2d 837, 847 (2d Cir. 1942).

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

273. *See, e.g.*, Donner v. Sheer Pharmacal Corp., 64 F.2d 217, 223 (8th Cir. 1933); United Chromium v. Int'l Silver Co., 53 F.2d 390, 394 (D. Conn. 1931).

274. 253 F.2d 156 (4th Cir. 1958).

Lectures at Harvard Law School.[275] All this was not lost on the lawyers or judges in the case. 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.[276] As in the case of Parke-Davis and adrenalin, the isolated and purified product quickly supplanted the crude extracts previously on the market.[277] 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.[278]

The Fourth Circuit reversed. Strikingly, the court dismissed outright the notion of a categorical product-of-nature bar and stated that "where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained."[279] Citing *Parke-Davis* "illustratively," but following its reasoning closely, the court upheld the patent based on the troika of *Parke-Davis*, *Kuehmsted*, and *Union Carbide*.[280] 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."[281]

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 Brothers* 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* itself 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.[282]

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275. LEARNED HAND, THE BILL OF RIGHTS (1958).

276. *Merck & Co*., 253 F.2d 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.

277. *Id.* at 158.

278. Merck & Co. v. Olin Mathieson Chem. Corp., 152 F. Supp. 690, 694-700 (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.

279. *Merck & Co.*, 253 F.2d at 162.

280. *Id*. at 162-63.

281. *Id.* at 164.

282. *See, e.g.*, John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I),* 85 J. PAT. &

The next step in the ascendancy of *Parke-Davis* 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*.[283] The most forceful reference to Hand's decision appeared in the pro-patentability opinion of Judge Giles Rich, then on the Court of Customs and Patent Appeals and by some distance the most influential patent judge of his era. Rich 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."[284]

The apotheosis of *Parke-Davis* arrived in the 1990s and 2000s, on the heels of the first gene patents.[285] 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 material.[286] The product-of-nature doctrine "all but disappear[ed] as a serious concern."[287]

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."[288] The Guidelines then gave three examples: a patent for yeast issued to Louis Pasteur in 1873, a 1970 case

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TRADEMARK OFF. SOC'Y 301, 322 n.151 (2003) (observing that *Latimer* was not cited in judicial opinions until the *Bergy* and *Chakrabarty* cases).

283. *In re* Bergy, 596 F.2d 952, 975 (C.C.P.A. 1979), *vacated*, Diamond v. Chakrabarty, 100 S. Ct. 969 (1980).

284. *Id*.

285. *See generally* Daniel Kevles and Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233 (2001) (discussing the early phase of patenting for DNA sequences).

286. 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.*, John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041 (2011); Jonathan Masur, *Patent Inflation*, 121 YALE L. J. 470 (2011).

287. *Conley & Makowski, supra* note 285*,* at 380.

288. Utility Examination Guidelines, *supra* note 7, at 1093.

involving extracted prostaglandins, and—accompanied by extensive quotation—Judge Hand's opinion in *Parke-Davis*.[289]

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.[290] 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."[291]

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[292]—the attention paid to *Parke-Davis* in current litigation is already providing a useful corrective. 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."[293]

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

Back, then, to *Myriad*, the gene-patent challenge. There are signs that the appellate litigation process has gradually weeded out some of the historical misconceptions surrounding the product-of-nature bar and its key precedents.[294] Similarly, discussion of the exception for isolated materials

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289. *Id*. (citing Improvement in the Manufacture of Beer and Yeast, U.S. Patent No. 141,072 (filed May 9, 1873) (issued Jul. 15, 1873) (issued to Louis Pasteur); *In re* Bergstrom, 427 F.2d 1394, 1397 (CCPA 1970)). Pasteur's patent is much cited in this context, but appears to have been an outlier. P.J. Federico, a senior official and preeminent historian of the U.S. Patent Office in the first half of the twentieth century, believed Pasteur's patent to have been "unique in patents in respect to its subject-matter." P.J. Federico, *Louis Pasteur's Patents*, 86 SCIENCE 327, 327 (1937).

290. Utility Examination Guidelines, *supra* note 7, at 1093.

291. *Id.*

292. *See generally* Conley & Makowski, *Part II*, *supra* note 285, at 386-87 (addressing concerns about the Patent Office's approach).

293. Amendment to U.S. Patent No. 35,546, Transcript of Record, *supra* note 158, at 888.

294. 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

seems to have moderated: rather than arguing that Learned Hand's decision in *Parke-Davis* was erroneous, the challengers' brief on appeal in *Myriad* distinguished the case[295] and argued that the opinion's broad dicta were overruled by later decisions.[296] In discussing isolation and purification, the U.S. Government's heavyweight amicus brief placed *Parke-Davis* into context alongside *Kuehmsted* to argue that patentability depends on a difference of kind rather than on purification *per se*.[297]

Nevertheless, how to treat *Parke-Davis*—and the whole isolated-materials line of cases—as legal authority remains a tricky question for the courts. As a District Court case, the precedential authority of Hand's opinion itself 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 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. This is the requirement that I have referred to as "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 *Myriad*, 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 U.S. Supreme Court going forward.

Judge Lourie's opinion upholding the BRCA claims[298] 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."[299] Extraction itself provides part of the

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and Cochrane cases into the discussion. *See, e.g.*, *Ass'n for Molecular Pathology I*, 653 F.3d 1329, 1350 n.6 (Fed. Cir. 2011) (disregarding these two cases as having been "decided based on lack of novelty, not patentable subject-matter").

295. The challengers 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 for the Appellees at 48, *Ass'n for Molecular Pathology II*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2010 WL 5311467.

296. *Id.* at 48-49.

297. Brief of the United States as Amicus Curiae, *supra* note 10, at 29-30.

298. 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.

299. *Ass'n for Molecular Pathology II*, 689 F.3d at 1328.

basis for this conclusion. Judge Lourie argues 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."[300]

With this move, Judge Lourie simply side-steps the crucial problem for the would-be patentee of a product of nature. If DNA isolation definitively changes the source material, rather than merely abstracting it from its natural setting, then the case for patentability is vastly easier to establish under the governing Supreme Court precedents: *Funk Brothers*, denying protection to unmodified organisms, is distinguished, while *Chakrabarty*, allowing a patent for a "nonnaturally occurring . . . product of human ingenuity," is satisfied.[301]

It is in this context that *Parke-Davis* makes a guest appearance in Judge 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.[302] By contrast, "the claimed isolated 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.[303] 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."[304] In constructing this test, Moore rests on the same Supreme Court precedents as Judge Lourie, *Funk Brothers* and *Chakrabarty*, but reads these cases to emphasize the need for useful difference.[305]

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300. *Id*. at 1329.

301. *Id.* at 1338 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

302. *Id.* at 1328 ("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.'").

303. *Id*. at 1329.

304. *Id.* at 1338 (Moore, J., concurring in part) (quoting *Chakrabarty*, 447 U.S. at 309-10; Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948)).

305. For example, she writes:

> 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. 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. Although the two cases result in different outcomes, the inquiry itself is similar.

Id. (citations omitted).

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*."[306] 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"[307] and demonstrate a consistent and "longstanding flexible approach."[308] This is a new slant on *Funk Brothers* 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 *Myriad*, finding sufficient new utility in the isolated DNA sequences to sustain their validity.[309] By contrast, Judge Bryson's dissent sides with the District Court in finding the relevant patent claims invalid.[310] 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."[311] 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."[312]

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.[313] It does, however,

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306. *Id*.

307. *Id.* at 1334.

308. *Id.* at 1339.

309. *Id.* at 1341-1343. 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 1341. 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." *Id.* at 1343. Despite the literal chemical difference, "[t]he isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature." *Id.* However, the "settled expectations" of an inventing community long used to obtaining gene patents tip the scale in favor of patentability. *Id.*

310. *Id.* at 1348 (Bryson, J., concurring in part and dissenting in part).

311. *Id.* at 1352.

312. *Id.* at 1354.

313. *Id.* at 1338 (Moore, J., concurring in part); *id.* at 1350 (Bryson, J., concurring in

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 reasoning means we might expect to see more of *Parke-Davis* as the gene-patent question proceeds to the Supreme Court.

CONCLUSION

Anyone looking for a historical "right" answer on the product-of-nature question will be disappointed. For all the spirited attempts to impose consistency on the case law of natural subject matter, it remains a kaleidoscope of doctrine: cases come at the question from different angles, in different historical contexts, with premises ranging from pragmatic to formalist and from patent-friendly to fiercely patent-skeptical. The same applies to the history of patent practice. Based on the evidence gathered above, we can say that patents for isolated (and/or barely modified) products of nature have been issued at some times, disdained at others, and have in some instances, such as the hormone patents of the 1930s, issued from the Patent Office even as the judicial climate turned against them.

Even so, there are a few lessons we can draw from the history. Two stand out. One is that the historical foundations of the bar on patenting products of nature are surprisingly shaky. The prohibition on patenting laws of nature represented a separate set of concerns about scope and abstract claiming, which failed to supply either clear authority or a clear nature/application-of-nature guiding line for product patentees. Meanwhile, before the twentieth century, there was no jurisprudential category of "natural" products, only a set of rules about novelty and distinctiveness from the prior art that applied across technologies, without regard to natural origin. The purported great exception, *Ex parte Latimer*, was surprisingly marginal: unknown to the courts, it may have presented occasional claim-drafting challenges for patentees such as Takamine, but did not effectively block the patenting of broadly natural subject matter, either in its own time or later. Only in the 1920s did a clutch of stronger product-of-nature statements emerge from the federal circuit courts, staking out categorical language against patenting products of nature, but giving no indication that they had a precedential basis to rest on.

By that time, of course, the law had opened up a space for patenting isolated natural substances. Again, this development emerged without a natural/non-natural distinction being made; instead, the doctrine of "useful difference" arose in the chemical sector, was duly applied by Learned Hand in

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part and dissenting in part) (both quoting Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980)).

the *Parke-Davis* case, and proved to be a legal gateway for isolated biological compounds that could demonstrate sufficient practical usefulness to constitute patentable difference over the prior art. As a historical matter, the traditional understanding of the doctrine is backwards:[314] rather than appearing as an "isolation and purification exception" to the ban on patenting products of nature, the isolation-and-purification patents came first, and the case law against patenting natural products arrived only later.

Time will tell if the useful difference test becomes the framework for DNA patenting in the future. As I have suggested, the idea that great enough new utility can convey sufficient novelty on an isolated natural product is not a major feature of the two cases (*Funk* and *Chakrabarty*) allegedly guiding the Federal Circuit's *Myriad* opinions. Reading those cases that way, as Judges Moore and Bryson arguably do, depends on imbuing them with the spirit of Judge Hand's *Parke-Davis* ruling. This approach allows for a highly pragmatic rule of patentability, focused on rewarding valuable inventions if the circumstances warrant, and deployable (as Judge Moore's opinion shows) to avoid the disruption and recrimination that would accompany mass invalidation of isolated DNA patents. Such pragmatism would be much in the tradition of Learned Hand. Whether it is the best course or not, the courts will have to decide.

Finally, the history tells a story about how patent law and its wider context change each other. Formal legal doctrine aside, the events of the adrenalin battle left their mark on the medical and scientific world in which they arose. Patenting in the life sciences became an un-ignorable fact of life in the twentieth century, and—whatever the outcome of *Myriad*—will continue to be in the twenty-first. From where we stand now, it is striking to look back to the point when the American pharmaceutical industry and the medical profession turned away from patent-skepticism and embraced the propriety of patent rights. 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.

314. *See, e.g.*, Gipstein, *supra* note 203.