# THE ISOLATION AND PURIFICATION EXCEPTION TO THE GENERAL UNPATENTABILITY OF PRODUCTS OF NATURE

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## I. Introduction

Section 101 of the Patent Act defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof."[2] However, in order to be patentable, a patent-eligible invention must meet additional requirements including, *inter alia,* the requirements of novelty and nonobviousness as imposed by Sections 102 and 103 of the Act, respectively. As Judge Rich once announced, determining what constitutes statutory subject matter under section 101 "has proved to be one of the most difficult and controversial issues in patent law."[3] Perhaps the crux of this difficulty arises from the failure of most courts to understand the difference between the requirements of section 101 giving rise to patent-eligibility, and the other sections' requirements of patentability.[4] Indeed, Judge Rich has expressed this opinion while commenting on the Supreme Court's decision in *Parker v. Flook*[5]:

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[2] 35 U.S.C. § 101 (2001).

[3] *In re Walter*, 618 F.2d 758, 764 (C.C.P.A. 1980).

[4] Michael A. Sanzo, *Patenting Biotherapeutics*, 20 Hofstra L. Rev. 387, 391 (1991).

[5] *Parker v. Flook*, 437 U.S. 584 (1978).

> [We] find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the categories of inventions in § 101 [of the Act] which may be patentable and to the conditions for patentability demanded by the statute for inventions within the statutory categories . . . Thus, the questions of whether a particular invention is novel or useful are questions wholly apart from whether the invention falls into a category of statutory subject matter.[6]

When a patent that claims a "product of nature" is rejected, it is generally done so for a lack of patent-eligibility under § 101. It is apposite to note, however, that there is nothing in any section of the Patent Act that expressly forbids the patenting of a product of nature. Therefore, the precise foundation for the general unpatentability of a product of nature remains somewhat ambiguous.[7] This leaves the limits of the doctrine lacking proper delineation and the patent community with a rather mushy understanding of what constitutes a product of nature, perhaps explaining why some have described the doctrine as serving more as "a source of confusion rather than a pillar of instruction."[8] Nevertheless, it remains generally accepted that those discoveries which unambiguously claim a product of nature are not patentable, irrespective of the particular legal authority that mandates this result. As Justice Douglas once stated in a famous case involving the mixture of three types of naturally-occurring bacteria:

> [P]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the

[6] *In re* Bergy, 596 F.2d 952, 959-61 (C.C.P.A. 1979) (emphasis omitted).

[7] Sanzo, *supra* note 4, at 391-92.

[8] Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. Rev. 961, 985 (1996).

> qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of the laws of nature, free to all men and reserved exclusively to none.[9]

The Supreme Court has never abandoned this position. However, thirty-two years after its decision in *Funk Brothers*, in its most recent opinion discussing the products of nature doctrine, the Supreme Court found that a genetically manipulated strain of bacteria, designed to degrade hydrocarbons, was not a product of nature.[10] Although the only certified question in that case was whether living things constituted appropriate subject matter for patent protection,[11] the essential holding of the Court was that life forms are not necessarily products of nature. The Court placed the bulk of its reasoning on the absence of explicit statutory authority to the contrary, greatly expanding the scope of § 101, and with it, the confusion regarding the meaning of a "product of nature."

Perhaps the most important, and undoubtedly the most difficult question that the Supreme Court has declined to answer is: *what*, precisely, *is* a product of nature? The *Chakrabarty* Court said that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter."[12] However, in the same opinion, the Court held that a genetically altered bacterium is patentable subject matter.[13] Therefore, all that is clear is that on the one hand, natural things left unchanged by human hands are

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[9] *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130 (1948) (citation omitted).

[10] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[11] *Id.* at 306.

[12] *Id.* at 309.

[13] *Id*. at 318.

products of nature and, therefore, not patentable; on the other hand, some natural things are so changed by human hands that they cease to be products of nature and are, thus, patentable. The ambiguity lies in determining where on the spectrum of human intervention a natural product, changed by human hands, ceases to be a natural product. This paper explores the isolation and purification exception to the products of nature doctrine, an exception first announced by Learned Hand in a 1911 case upholding a product patent on purified adrenaline,[14] in an effort to shed some light on this question.

## II. The constitutional implications of the products of nature doctrine

It seems that the underlying logic behind granting patent protection for things that are derived from nature, while at the same time denying patent protection for things that have always existed in nature, is constitutionally sound. In fact, it may be constitutionally mandated. After all, the stated purpose of the constitutional grant of authority to Congress to pass the Patent Act is "to promote the progress of science and useful arts."[15] While it certainly promotes the progress of science to reward those who innovate and are first to add an invention to the storehouse of knowledge, it does not promote the progress of science to reward those whose alleged invention adds nothing. To harness this logic in the products-of-nature context, the assumed fact must be that things that have always existed in nature are already part of the storehouse of knowledge, a well-accepted principle deeply rooted within nearly every Supreme Court decision

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

[15] U.S. Const. art. I, § 8, cl. 8.

dealing with the subject. For example, in *Funk Brothers*, the Court, in the name of the products of nature doctrine, expressly prohibited a patent from issuing "on one of the ancient secrets of nature now disclosed."[16]

While this assumed fact is certainly well accepted, the source of its authority is ambiguous. As previously iterated, the courts tend to commingle the statutory provisions when making rulings dealing with products of nature. However, whether the legal justification lies within the patent-eligibility requirement of § 101, or within the novelty or nonobviousness requirements of § 102 and § 103, seems immaterial. The fact remains that all courts agree that a product of nature is not patentable. The difficulty arises from determining what, precisely, is a product of nature. The statutory provisions do not speak to this difficulty. Thus, it may be preferable to disregard the statutory provisions altogether, and determine whether an invention is a product of nature by conducting a constitutional analysis.

The Intellectual Property Clause is designed to doubly benefit the public through the grant of exclusive rights to inventors.[17] A present benefit is derived from immediate access to innovations, although tempered by high monopoly pricing; a future benefit is derived when, after the finite term of patent protection expires, the work falls into the public domain, and "the public finally receives the full benefit of Congress's purchase in

[16] *Funk Brothers*, 333 U.S. at 132.

[17] Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. Ill. L. Rev. 1119, 1165 (2000).

its name."[18] Indeed, it is from this future benefit to the public of free access to the inventor's work that the principle of an inviolable public domain follows as a necessary implication.[19] The Supreme Court has expressly recognized this constitutional limitation on Congress's authority to grant patents for items already within the public domain: "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available."[20] It therefore follows that the invalidation of patents claiming products of nature, which have been deemed by the Supreme Court to be "free to all men and reserved exclusively to none,"[21] is constitutionally mandated. There need not be any statutory authority to deny patents that claim products of nature.

This result may prove to be quite convenient. After *Chakrabarty* made use of such an expansive reading of § 101, numerous Federal Circuit cases have followed the lead, increasing § 101's scope to the extent that it is now questionable whether § 101 has any bite left at all. This leaves the only statutory authority on which to base a product-of-nature rejection in the proverbial hands of § 102 and § 103. The problem is that these sections were not written to deal with products of nature, and so it is exceedingly difficult to maintain consistency within a legal framework that otherwise embodies our

[18] *Id.*

[19] *Id.*

[20] *Graham v. John Deere Co.,* 383 U.S. 1, 5-6 (1966).

[21] *Funk Brothers*, 333 U.S. at 130.

conceptions of novelty and nonobviousness. For example, it would be awkward to suggest that a new fiber present in the needle of a particular species of tree, unknown in the prior art and far better suited for industrial purposes, is not novel within the specific meanings of each of the statutory criteria set forth in § 102. Natural products can be novel. Indeed, if courts are permitted to restate the product of nature doctrine in terms of novelty, they have no difficulty finding patentability:

> It seems to us that the answer to that question whether or not the purified prostaglandin was novel is self-evident: by definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing . . . the "pure" materials are "new" with respect to them.[22]

Likewise, it is not reasonable to suggest that the invention is obvious under § 103. However, it remains well settled that the fiber described above is not patentable because it was extracted from a natural source and so it was a product of nature, even though it was not known in the prior art.[23] Thus, it seems that the concept of an inviolable public domain, mandated by the Constitution, should actually be viewed as comprising two separate doctrines: 1) things already known to mankind, and therefore adequately described by § 102 and § 103 of the Patent Act, are not patentable; and 2) things that exist naturally, or products of nature, are not patentable. The two need not be conceptually related, beyond both being corollaries of the principle of an inviolable public domain. If viewed in this way, there is no need to find support for the products of

[22] *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970).

[23] *Ex parte Latimer*, 1889 Dec. Com. Pat. 123.

nature doctrine within the statutory framework, and it follows that the fiber patent can be invalidated even though it may technically claim novel subject matter.

Perhaps it may be successfully argued that § 101 appropriately applies to exclude the fiber from patent-eligibility, but it is hard to do this consistently. As the scope of § 101 is increasingly expanded to encompass the full breadth of the authority delegated to Congress by the Constitution, it appears that the only remaining place to find the consistent and unambiguous authority to deny patent protection for products of nature is within the Constitution itself. Therefore, the products of nature doctrine should be recognized as being of constitutional origin and evaluated accordingly.

In any event, it is undisputed that products of nature are not patentable, irrespective of the legal authority that mandates this result. The underlying difficulty, which is certainly exacerbated by the ambiguity in sorting out the legal authority, deals with defining what precisely constitutes a product of nature. The line between what has always existed in nature and what is a recent development is extremely difficult to draw, especially considering that in some sense everything is a product of nature. This difficulty has led to a bifurcation in the case law, focused predominantly in the area of biochemical sciences, dealing with the unpatentability of products of nature in general, but carving an apparent exception for "biotherapeutic" purified natural substances.

## III. The origin of the purification exception to the products of nature doctrine

Despite the Supreme Court's consistent declaration that products of nature lie outside the scope of the Patent Act, a second line of cases seems to have developed, permitting the patenting of "purified" natural products. This doctrine can be traced back to a Learned Hand opinion in a 1911 case involving the isolation and purification of human adrenaline from the suprarenal glands.[24] It is important to note that Hand upheld a *product* patent for the purified adrenaline, not merely a *process* patent, or even a *product-by-process* patent.

In *Parke-Davis*, the examiner had originally rejected the patentee's claims based upon the examiner's interpretation of the wood paper patent case.[25] The examiner believed that this case stood for the proposition that no product patent is possible, even if the product was obtained by a novel process, if it is merely separated from its surrounding materials and remains unchanged.[26] In order to get around this, the patentee (Takamine) took the salt form of adrenaline, which is the form naturally found in the suprarenal gland, and chemically converted it into a base during his purification

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

[25] *American Wood-Paper Co. v. Fibre Disintegrating Co*., 90 U.S. 566 (1874).

[26] *Parke-Davis*, 189 F. at 101.

process.[27] The examiner thereafter issued Takamine a product patent for his purified adrenaline base. Learned Hand upheld the patent, further stating that "even if it were merely an extracted product without change, there is no rule that such products are not patentable."[28] It is clear that Hand disagreed with the examiner's interpretation of the wood paper patent case.

That case concerned a new chemical process for the manufacture of paper. Before the felting of paper is possible, the materials out of which the paper is made must be reduced into what is called "pulp." Pulp is a fibrous material consisting of cellulose and can be obtained from wood or other vegetable substances. In its natural state, the pulp is combined with many other substances, known as intercellular matter, which must be removed in order to prepare the cellulose for manufacture. At the time of filing, it was well understood that wood contained the necessary cellulose, but there were no known processes by which the cellulose could be purified by means of chemical treatment alone. Mechanical processes were also required. The Court found:

> It is quite obvious that a manufacture, or a product of a process, may be of no novelty, while, at the same time, the process or agency by which it is produced may be both new and useful . . . and, therefore, patentable as such. It is equally clear, in cases of chemical inventions, that when, as in the present case, the manufacture claimed as novel is not a new

[27] Note that the chemical nomenclature "salt" refers to the dehydrated chemical product that is created when an acid is combined with a base. Thus, table salt, known as sodium chloride, NaCl, and water, HOH ($H_2O$), can be formed by combining sodium hydroxide, NaOH, and hydrochloric acid, HCl.

[28] *Parke-Davis,* 189 F. at 103.

> composition of matter, but an extract obtained by the decomposition or disintegration of material substances, it cannot be of importance from what it has been extracted.[29]

The Court went on to explain that there are many things that are "valuable in medicine which may be extracted from diverse substances. But the extract is the same, no matter from what it has been taken."[30] If the patent is sustainable, it "must be because the product claimed . . . was unknown prior to their alleged invention."[31]

The patentee in that case tried to argue that his product was more pure than had previously been possible, even with the additional mechanical processes. He therefore concluded that his product was different, and merited patent protection. The Court did not agree, holding that a slight difference in the degree of purity of an article produced by several processes should not justify a patent, especially when the design of the product and its end-use are the same for all processes.[32]

Learned Hand did not discuss this case at all, aside from noting that it was the source of the examiner's rejection. Instead, he simply asserted:

> [T]he base was an original production of Takamine's. That was a distinction not in degree, but in kind. 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

[29] *American Wood Paper,* 90 U.S. at 593.

[30] *Id.* at 593-94.

[31] *Id*. at 594.

[32] *Id.*

> 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.[33]

At this point, Hand declared that the therapeutic value of the purified natural substance is good grounds for a patent, and he cited the famous aspirin case[34] and *Union Carbide*[35] as authority.[36] Although at first glance it may appear that Hand was following precedent in upholding the patent, after careful scrutiny we realize that he made an unfounded leap in logic, perhaps inadvertently, that created new law where none had existed before. In other words, it is impossible to logically deduce his holding from combining the precedents that he cited.

In *Union Carbide*, decided one year prior to *Parke-Davis* and also in the Second Circuit, the patent was for a new form of crystalline calcium carbide, having a bluish, purplish iridescence. The Court found that the crystalline product as described was different from the amorphous product known in the prior art because of its different physical properties.[37] The crystalline calcium carbide was much harder, more compact, was better suited for gas generators, and would not deteriorate when exposed to air. The Court stated that the patentablility of the compound rested solely on the basis of its

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[33] *Parke-Davis*, 189 F. at 103.

[34] *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910).

[35] *Union Carbide Co. v. American Carbide Co.,* 181 F. 104 (2d Cir. 1910).

[36] *Parke-Davis*, 189 F. at 103.

[37] *Union Carbide*, 181 F. at 107.

novelty.[38] It concluded that the crystalline product, due to its different characteristics that made it better suited for commercial use, marked a patentable difference over the amorphous product.[39] The Court never discussed the implications of the fact that the crystalline compound was a purified form of the previously known amorphous compound, focusing instead on their physical properties.

In the aspirin case, also decided one year prior to *Parke-Davis*, the Seventh Circuit upheld a product patent for a purified form of the synthetic chemical compound known as aspirin. It was found that the chemical composition of aspirin (acetyl salicylic acid) was known before the patentee filed, and that his discovery was really just a new process of obtaining the compound.[40] Specifically, his process involved the heating of salicylic acid with acetic anhydride as opposed to combining acetyl chloride with salicylic acid. It was found that the products of the two processes had different chemical behaviors. The Court muddled around in the chemistry with tremendous technical difficulty attempting to determine if the two products were in fact the same thing, and ultimately concluded: "two substances, having the same chemical formula, may differ widely, as to impurities, upon qualitative analysis."[41] As a result, the fact that two products have the same substance chemically does not mean that they have the same

[38] *Id.* at 106.

[39] *Id.* at 107.

[40] *Kuehmsted*, 179 F. at 703.

[41] *Id.*

substance physically, meaning that their chemical behavior, and thus their therapeutic value, may be widely different.[42] Therefore, the Court upheld the patent on the ground that the aspirin produced by the new process was in fact a novel substance and deserving of patent protection.[43] The Court also noted:

> It makes no difference, so far as patentability is concerned, that the medicine thus produced is lifted out of a mass that contained, chemically, the compound; for, though the difference between [the patentee and the prior art reference] be one of purification only – strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable – patentability would follow.[44]

Although this quote appears to embody the essential holding of *Parke-Davis*, when carefully scrutinized, the connection is illusory. Indeed, combining the authority from the wood paper patent case, the aspirin case, and *Union Carbide* does not logically add up to the holding in *Parke-Davis*. The wood paper patent case is properly restricted to cases in which the end product is unknown in the prior art. However, Learned Hand did not even discuss the authority of this case, which is bothersome because it appears that embedded within the Supreme Court's holding are implications about the patenting of all purified extractions from natural sources. The case explains that in order for the patent to be sustainable, the extraction must be an unknown product altogether, and the case specifically doubts the wisdom in granting patents for purified extractions:

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[42] *Id.*

[43] *Id.* at 705.

[44] *Id.*

> Whether a slight difference in the degree of purity of an article produced by several processes justifies denominating the products different manufactures, so that different patents may be obtained for each, may well be doubted, and it is not necessary to decide.[45]

However, aside from the statements about its dubious nature, it is clear that the Supreme Court did not specifically rule on the issue of whether the novelty of an extracted substance should be considered wholly apart from the substance from which it was extracted. In other words, the Court never really decided whether it is possible for a product, extracted from a source which is known in the prior art, to be itself unknown in the prior art.

At this point, Learned Hand turned to the aspirin case. In that case, he found convincing authority that a chemical, which was known in the prior art, can be patented in a more pure form if the new form has therapeutic value well beyond that of the old form. Therefore, it would seem that the aspirin case offers authority which would fill the gap left by the wood paper patent case, together leading to the holding in *Parke-Davis*. The problem is that the *Parke-Davis* and the wood paper patent cases are about extractions from naturally occurring sources. The aspirin case is about a chemical that was originally manufactured by man. The difference is significant. On the one hand, in the aspirin case, the Seventh Circuit in essence ruled that the therapeutic value of a man-made chemical is important in determining its novelty. If the previously known product is less useful, then it seems to go against the fabric of the patent law not to allow the

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

newly purified, and much more valuable, product patent protection. On the other hand, in *Parke-Davis*, Learned Hand is holding that this philosophy may be extended to naturally occurring products, allowing patent protection for the purification of products that man did not invent. The problem is at the heart of the distinction between novelty and natural product. Is it really appropriate to use the same test for both? Learned Hand, perhaps inadvertently, held that it was.

We would reach the same result if we rely, instead, on *Union Carbide*. In that case, the Court reached a result similar to the aspirin case, although the product in question was not biologically active. The product was found to be a novel chemical because its physical characteristics were different from those known in the prior art, and again, the product was originally man-made, and not a natural product. Indeed, it is crucial to realize that neither the aspirin case nor *Union Carbide* dealt with natural products. Both had to do with finding a patentable difference in the purified form of an originally man-made chemical, the difference giving rise to a new use. It is true that the aspirin case involved a chemical that was biologically active, but no discussion of natural products was necessary because aspirin is an artificial compound. This pinpoints the gap in the logical deduction that Learned Hand made in *Parke-Davis*: no court had ever allowed a purified *natural* product to receive patent protection. In fact, it appears that Hand completely ignored this line of cases which had specifically held purified natural products to be unpatentable.

## IV. *Parke-Davis* did not cite case law denying patents for purified natural products

The bottom line is that at the time of *Parke-Davis*, the aspirin case and *Union Carbide* illustrate an interesting but unspoken divergence in the line of cases dealing with purifications. One line dealt with the purification of man-made products, finding novelty in new uses, such as the development of therapeutic availability, etc. It was found that some differences marked a patentable advance, although the precise standard of what marked a patentable advance was left largely unanswered. The other line of cases dealt more with purified *natural* substances. This line generally led to the denial of patent protection, and more often than not involved the purification of naturally occurring elements or the purification of extractions taken from naturally occurring materials, where the only work of man was in the purification. In some sense, this bifurcation in the case law anticipated the distinction between *Funk Brothers* and *Chakrabarty*, depending largely upon whether the end product was properly considered man-made.

The wood paper patent case is an example of the latter line of cases. However, as previously shown, the holding of that case is less useful to illustrate the unpatentability of products extracted from natural sources *in general* because, in that case, the final product was already known in the prior art. A better example of the law before the time of *Parke-Davis* is *Ex Parte Latimer*.[46] That case involved a patent on a fiber present that was discovered in the needle of a particular species of tree, Pinus Australis, which was far

[46] *Ex parte Latimer*, 1889 Dec. Com. Pat. 123.

superior to any other fiber known at that time. The Court found that the fiber was not patentable because it was extracted from a natural source, and so the product was naturally occurring, irrespective of how beneficial its properties may have been.[47]

This line of cases came to deal primarily with purified, naturally occurring elements.[48] The ruling in *Parke-Davis* apparently had no effect on these cases because several of them are found chronologically after the ruling in *Parke-Davis*. Take, for example, the 1928 Third Circuit case where General Electric sued for infringement of its patent on pure tungsten.[49] The patentee had developed a process to convert tungsten, a brittle metal in its natural state, into an element of great ductility and high tensile strength, in a reaction that "seemingly created a chemical paradox."[50] The 'new' metal had numerous uses that it did not have previously; specifically, it was suitable to be drawn into a wire to be used as a filament in a light bulb or in a vacuum tube. The court found that the 'new' metal was not patentable because it was not new at all. In fact, the chemical paradox was easily resolved. The patentee had merely isolated pure tungsten from its oxide, $WO_3$, which is the form normally found in the earth. The oxide is brittle, but pure tungsten is not.

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[47] *Id.* at 125-26.

[48] Michael D. Davis, *The Patenting of Products of Nature*, 21 Rutgers Computer & Tech. L. J. 293, 323-34 (1995).

[49] *General Electric Co. v. De Forest Radio Co.,* 28 F.2d 641 (3d. Cir. 1928).

[50] *De Forest*, 28 F.2d at 642.

The Court would not let the patentee obtain exclusive rights on an "element of nature with characteristics that nature alone has given it."[51] Indeed, the Court reasoned that the relevant question was:

> [W]hether the tungsten of which the patent speaks is the tungsten of nature with its inherent quality of ductility or is a new metal produced by Coolidge which is wholly different from anything that nature provides.[52]

The Court explicitly stated that Coolidge, the patentee, had indeed "purified" the metal, taking the tungsten as it existed in nature, as its oxide, and converting it into a substantially more useful product, where the characteristics were "wholly different from the characteristics of the impure oxide,"[53] but concluded that Coolidge had not created these characteristics. The court questioned whether the invention could properly be considered man-made:

> Naturally we inquire who created pure tungsten. Coolidge? No. It existed in nature and doubtless has existed there for centuries. The fact that no one before Coolidge found it there does not negative its origin or existence.[54]

The Court invalidated Coolidge's patent. This case is still good law and perfectly exemplifies the general 'products of nature' case at the time of *Parke-Davis*. It is interesting to realize that the Court did take note of the fact that the patentee had not

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[51] *Id.*

[52] *Id.*

[53] *Id*. at 643.

[54] *Id.*

sought a patent for a new composition of matter, but had instead claimed a product that later proved to be tungsten.[55] However, this is apparently not an important distinction to make; several cases followed in the Court of Customs and Patent Appeals where numerous patents were filed under exceedingly similar fact patterns, claiming a new composition of matter, but still not granted. For example, in *In re John Wesley Marden and Malcolm N. Rich*,[56] the Court of Customs and Patent Appeals rejected the patentees' claim for ductile vanadium. In this case, counsel on both sides stipulated that the ductile vanadium was "nothing more or less than vanadium freed from all of its impurities and that all pure vanadium is ductile."[57] The Court invalidated the patent without more, stating that the ductility of the vanadium is "one of its inherent characteristics"[58] and not a characteristic given to it "by some chemical reaction or agency which changes its inherent characteristics."[59] *In re John Wesley Marden*,[60] the companion case, denied patent protection for ductile uranium.

If the legal formulation created by these natural products cases is the appropriate formulation for all purified natural products, then *Parke-Davis*'s adrenaline product could

[55] *Id.* at 642.

[56] *In re John Wesley Marden and Malcolm N. Rich*, 47 F.2d 958 (C.C.P.A. 1931).

[57] *Id.* at 958.

[58] *Id.*

[59] *Id.*

[60] *Id.* at 957.

not have passed muster. The bottom line is that all of these cases have found it critical that the patentee did not give the product its characteristics. All of them deal with a patentee finding an unpurified natural substance, developing a process for isolating the part that is useful, and then purifying the isolated extract. The courts have all held that a product is not patentable, no matter how useful it proves to be, if the patentee did not give the product its physical characteristics. Perhaps this language is a bit misleading because, in actuality, there is no way for anyone to give anything its physical characteristics; in some sense, everything is natural. However, the courts have made clear that there is definitely a point on the spectrum of human intervention where the workmanship of man can no longer be ignored, such that a product ceases to be 'natural.' Indeed, the courts have upheld countless patents for 'new' chemicals, meaning first synthesized by man, and for 'new' elements, meaning first created by man. For example, in *In re Seaborg*[61] the court upheld a patent for man-made curium, an element not known to exist on earth prior to the invention. In the companion case,[62] the court upheld a patent for man-made americium, likewise unknown prior to the invention. These cases would seem to anticipate the distinction made by the *Chakrabarty* court, some fifteen years later, in attempting to draw the line between natural and man-made products.

It is safe to say that *Parke-Davis*' adrenaline product is not a new composition of matter in the same way that a synthetically created molecule is, or an element never

[61] *In re Seaborg*, 328 F.2d 993 (C.C.P.A. 1964).

[62] *Id.* at 996.

before existing on this planet is. The adrenaline in question was a purification of an existing composition of matter. This is not to say that courts before *Parke-Davis* had never found novelty by purity before; in fact, as we have seen, they had. However, courts had previously limited this inference of novelty to situations where the prior art was itself man-made, although it appears that this limitation was not explicit. Therefore, if it had not been for Learned Hand's legal innovation, and the court had followed the previous line of cases, the adrenaline patent in *Parke-Davis* would have been invalidated. This becomes abundantly clear if one reads the opinion of *De Forest Radio*, and replaces the word "tungsten" with "adrenaline," along with a few other necessary changes, such as follows: the relevant question is "whether the [adrenaline] of which the patent speaks is the [adrenaline] of nature with its inherent [mechanism of action] or is a new [molecule] produced by [Takamine] which is wholly different from anything that nature provides."[63] In order to answer this question, "naturally we inquire who created pure [adrenaline]. [Takamine]? No. It existed in nature and doubtless has existed there for centuries. The fact that no one before [Takamine] found it there does not negative its origin or existence."[64]

So we conclude that the patent in *Parke-Davis* would have been invalidated if Learned Hand had followed the rule in *De Forest Radio,* or in *Ex Parte Latimer*, or in any of the other cases in that line of reasoning. This does not necessarily mean that

[63] *De Forest,* 28 F.2d at 642.

[64] *Id.* at 643.

*Parke-Davis* went wholly against the grain of the patent system. On the contrary, it would seem that if the process of isolating and purifying adrenaline is expensive and difficult, then providing incentives to do so is fully consistent with the economic purpose of the patent law system and the underlying principles of the Intellectual Property Clause.[65] However, the competing interest of protecting the public from having alleged inventors withdraw knowledge from the public domain is tremendous. Thus, Hand's legal innovation in *Parke-Davis* drives a sharp wedge between the economic and formalistic ideologies within patent law, and one would conclude differently as to whether the result in *Parke-Davis* was appropriate depending on which ideology one embraces.

It is certainly true that *Parke-Davis* has created vast financial incentives for scientists to conduct, and for investors to bankroll, biotherapeutic research and development, which has unquestionably benefited society. However, it is also true that until *Parke-Davis* was decided, there was no formal legal doctrine permitting a purified natural product to be patented; the existing doctrine allowed only for purified man-made products to defeat the novelty requirement of § 102. Recall that deciding whether something is a product of nature is wholly separate from deciding whether it is novel. Therefore, as far as a formalist is concerned, Hand is guilty of commingling the statutory

[65] Heald & Sherry, *supra* note 17, at 1165.

requirements by declaring the adrenaline product patentable because it was novel, as opposed to addressing the issue that it may have been a product of nature.

Whether the adrenaline was, in fact, a product of nature is another formalist question that Hand sidestepped altogether, probably inadvertently. It is interesting to note that aside from being the first case to uphold a patent for a purified natural product, *Parke-Davis* is also cited as one of the first cases where the judge expressed an extreme discomfort with the technical matters and asked for future evidentiary assistance from scientific experts:

> The court summons technical judges to whom technical questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken. How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows . . .[66]

Take Hand's frustration into account while reconsidering his assertion that: "Everyone, not already saturated with scholastic distinctions, would recognize that Takamine's crystals were not merely the old dried glands in a purer state."[67] It would appear that Hand was trying to simplify an extremely complicated problem, reducing the formalist question of whether the purified adrenaline was still a product of nature into an economic question of whether the product was practically the same thing as the substance from which it was extracted. It is certainly true that everyone not already saturated with

[66] *Parke-Davis*, 189 F. at 115.

[67] *Id.* at 103.

scholastic distinctions would also recognize that Coolidge's pure tungsten was practically different from the brittle metal found in the core of the earth; however, the adrenaline was patentable and the tungsten was not. It would seem that Hand was performing brain surgery with a monkey wrench; he never even considered the fundamental question whose answer was prescribed by his opinion.

As previously iterated, the wisdom of Hand's prescribed answer is determined by one's outlook on the patent system in general. The economic argument is strongly in favor of allowing patent protection for purified natural products when those products are difficult and expensive to obtain. The formalist argument is strongly opposed to permitting an alleged inventor to remove knowledge from the public domain. After *Parke-Davis*, the prevailing view is to allow patent protection for purified natural products that are biotherapeutic in nature. Purified natural products that are not biotherapeutic in nature are, perhaps inexplicably, still held to be unpatentable. The intellectual quagmire is that if the economic argument is powerful enough to overcome the formalist's objection to the removal of natural products from the public domain, such that it is wise to grant patents on purifications of natural products, then how come the same is not true of non-therapeutic products? Why should the law single out the biotech industry for special treatment? The lack of a convincing answer to this question severely detracts from the weight of the economic argument.

## V. There is no fundamental difference between the biological and physical sciences

Aside from explaining *Parke-Davis* as a departure from the man-made versus naturally-occurring distinction, another way to interpret *Parke-Davis* is to find a fundamental difference between the biological sciences and the physical sciences. Hand insisted that he was upholding a patent for a substance that was "for every practical purpose a new thing commercially and therapeutically."[68] He did not believe that his decision amounted to upholding a patent for the purification of a natural substance, although he admitted that it may look that way when analyzed logically.[69] Therefore, he must have believed that the purified adrenaline product was fundamentally different from other purifications. Is it possible that biotherapeutics necessarily differ on an elemental level from paper pulp, fiber extracts, purified tungsten, or man-made curium?

Hand asserted that "the line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from the nice considerations of dialectic."[70] This argument certainly supports the conclusion that the purified adrenaline is patentable, but the problem is that it also supports the conclusion that the purified tungsten is patentable. Unless the argument somehow implicitly limits its applicability to bioactive molecules, then there is no formal way to distinguish products that *Parke-Davis* and its progeny hold patentable from those that *De Forest*

[68] *Id.* at 103.

[69] *Id.*

[70] *Id.*

*Radio* and its progeny hold unpatentable, creating a menacing legal inconsistency. It seems shocking that modern courts rule, perhaps without noticing, that purified products derived from natural sources are to be treated separately, depending on whether they contain biotherapeutic value. It is not disputed that the development of biotherapeutic molecules is extremely difficult, extremely expensive, and extremely important. But, so too is the development of nuclear capability. Yet, it would seem that the courts would permit the patenting of purified growth hormone, and would not permit the patenting of the fissile isotope of uranium, $U_{235}$, even though this isotope is extremely difficult to isolate, inordinately expensive to purify, and it marks the difference between those countries with the preliminary goods for nuclear power and those without.

One might wonder if the biological sciences must be treated differently from the physical sciences because, unlike in the physical sciences, scientists do not have the ability to simply create man-made biomolecules, they must be isolated from tissue and purified. Not only is this argument not scientifically accurate, but even if it were, its force is illusory. We cannot make a nucleus radioactive either; nature does the work, we just isolate it. Ultimately, every formal attempt to distinguish biology from physical science begs the question of what a product of nature really is. There is no formalist argument that supports the disparate treatment of these sciences in patent law. In essence, from a formalist's viewpoint, *Parke-Davis* combined two lines of reasoning that led to a third line of reasoning that lacked the logical force of either of its parents. Indeed, prior to *Parke-Davis*, purified man-made chemicals with new therapeutic value

were patentable. Products of nature, purified or not, were not patentable. Learned Hand made the jump to say that if a purified product of nature has therapeutic value, it is patentable. No case had ever held that before, and no case has ever held against that since. Viewed in this way, it appears that Hand created a "biological exception" to the products of nature doctrine.

It may well be argued that there are economic justifications for differential treatment of inventions within industries with different patterns of technical advance,[71] but no such argument explains *Parke-Davis*. The thrust of this type of argument tends to arise from a perceived difference in the way technical advances occur in different fields; at least four generic models are needed to explain these differences.[72] The first model describes the discrete invention, well defined and potentially improved upon, which "does not point the way to wide ranging subsequent technical advances."[73] The second model deals with cumulative technologies which tend to build upon themselves, allowing for dramatic advances over time.[74] The third model fits the chemical industry, having characteristics from both the discrete and cumulative models, depending on the

[71] Robert P. Merges & Richard R. Nelson, *On The Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839 (1990).

[72] *Id.* at 880.

[73] *Id.*

[74] *Id.* at 881.

possibility for future development.[75] While chemical inventions are most often discrete inventions that cannot easily lead to future advances, on occasion a chemical invention can lead to a whole new class of molecules with a wide variety of applications.[76] The fourth and final model describes science-based industries, where invention is predominantly driven by the external advancement of science, biotechnology being an obvious example.[77]

It has been argued that in a science-based industry, such as biotechnology, the courts should be more cautious about granting overly broad patents for fear of stunting the growth of the industry, which is by definition largely founded upon recent scientific advances.[78] If anything, this supports the proposition that Learned Hand should not have expanded the scope of patent protection available for inventors in the biotechnology field. However, the invention in *Parke-Davis* is probably best described by the third model, since the adrenaline product was merely a new pharmaceutical, not an external advancement in science or a result thereof. Therefore, since the industrial patterns of technical advance are apparently identical, this places Takamine's adrenaline product on the same exact footing as Coolidge's tungsten, or Marden's uranium, and so there is no justification for bifurcation in the case law.

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[75] *Id.* at 882-83.

[76] *Id.*

[77] *Id.* at 883.

[78] *Id.* at 915.

Recall that Learned Hand began a practice of upholding *product* patents for purified natural products. It has often been said that this practice results in an unnecessarily wide scope of patent protection.[79] Indeed, the patent on the adrenaline would have been infringed by the use of a wholly new and far better process for manufacturing the product.[80] Obviously, this is economically inefficient because it fails to achieve a balance between the scope of patentee's protection and his contribution to the art, resulting in a deadweight loss to society.

It makes one wonder what the full implications of this "biological exception" might be. Suppose researchers develop a revolutionary way to control the differentiation of stem cells such that they can be made to grow into any human "product" desired. Are these products patentable under *Parke-Davis*? Take the suprarenal glands, for example. Can an individual secure a patent on the genetically perfect suprarenal gland if he can create a line of stem cells that contains the perfect genetic sequences and can manipulate their differentiation? Certainly this would require the ability of the researchers to isolate the genes responsible for the development of the gland; so does this fall within the authority of *Parke-Davis*? It would seem that it depends on whether there is a fundamental difference between owning the rights to human adrenaline and owning the rights to the human organ that creates the adrenaline. After *Chakrabarty*, it appears that anything is appropriate subject matter for patent protection, and *Parke-Davis* seems to

[79] *Id.* at 903.

[80] *Id.*

suggest that if the product is "for every practical purpose a new thing commercially and therapeutically,"[81] which the organs would most certainly prove to be, then there would be little standing in the way of patent protection. Therefore, as an alternative to administering adrenaline directly, doctors would have the option of replacing the patient's suprarenal glands with a patented version. Whether this is a good thing or not is an entirely separate question, the point being that the scope of the purification exception is enormous, extending well beyond what Learned Hand could have possibly imagined in 1911. In fact, *Parke-Davis* may turn out to be the exception that swallowed the rule.[82]

## VI. Purity – a distinction in degree or a distinction in kind – all a matter of degree

Moving away from the subtleties of the products of nature doctrine and into the line of cases that followed *Parke-Davis*, there is a famous case that involved a dispute over the patentability of vitamin B-12.[83] For many years the scientific community was unable to isolate, or even identify, the active substance that was known to be located within the liver of cattle and used to treat anemia.[84] Finally, the patentee succeeded in isolating what came to be known as vitamin B-12. The patent claims did not cover pure,

[81] *Parke-Davis*, 189 F. at 103.

[82] John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 Emory L. J. 101 (2001).

[83] *Merck & Co., v. Olin Mathieson Chemical Corp.,* 253 F.2d 156 (4th Cir. 1958).

[84] *Id.* at 158.

crystalline vitamin B-12, but a composition whose purity was defined within a range of specified limits.[85] As a further limitation, the patent only covered compositions derived from the reactions of specified fermentates.[86]

In upholding the patent, Judge Haynsworth took the following view of the products of nature doctrine:

> There is nothing in the language of the [Patent] Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability.[87]

He went on to explain that *all* tangible things are products of nature because nature is the fundamental source of all material, thereby interpreting *Parke-Davis* to be an obvious corollary standing for the proposition that the products of nature doctrine is applicable only when the patented composition is not new and useful.[88] Essentially, Judge Haynsworth viewed the products of nature doctrine as being derived from the novelty requirements of § 102. Accordingly, he conjectured that the products of nature doctrine could actually be separated into two separate doctrines:

> (1) [A] patent may not be granted upon an old product though it be derived from a new source by a new and patentable process, and (2) that every step in the purification of a product is not a patentable advance, except,

[85] *Id.* at 157.

[86] *Id.* at 160.

[87] *Id.* at 161.

[88] *Id.* at 162.

> perhaps, as to the process, if the new product differs from the old 'merely in degree, and not in kind.'[89]

In defense of (1), he offered *American Wood Paper* as support. In defense of (2), he offered, *inter alia*, *Parke-Davis* and *In re Merz*.[90] As Hand before him, Judge Haynsworth explained that all improvements in purity do not amount to novel products; however, some improvements differ not merely in degree, but in kind. He quoted the *In re Merz* opinion as further support for this proposition: "if the process produces an article of such purity that it differs not only in degree but in kind it may be patentable. If it differs in kind, it may have a new utility in which invention may rest."[91]

Unfortunately, Judge Haynsworth's formulation of the products of nature doctrine does not shed light on any of the fundamental problems that were discussed above, but it does raise several interesting questions about the nature of finding novelty by purity. What precisely marks a difference in kind? At what point does an old product become a new product because of its purity? In *Parke-Davis*, the purified adrenaline was found to be a new product altogether. Hand asserted:

> [E]veryone, not already saturated with scholastic distinctions, would recognize that Takamine's crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals

[89] *Id.* at 161.

[90] *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938).

[91] *Id.* at 601.

> were obtained from the glands by a process of eliminating the inactive organic substances.[92]

So, apparently, Hand believed that at some point on the spectrum of purity, it becomes clear that the product is new and useful, and therefore merits patent protection. Yet, it remains clear, on the other side of the spectrum, that a less substantial increase in purity does not justify a product patent, leaving open only the possibility of a process patent, as described in *Merck*. Thus, the point on the spectrum where the additional increase in purity ceases to be a distinction in degree and becomes a distinction in kind, is really just a matter of degree, because a distinction in kind is nothing more than an adequate distinction in degree. In this sense, there is no such thing as a distinction in kind. If there were, it would imply a discontinuity in purity. Therefore, one must be cautious in construing the meaning of the language used by the courts in describing the appropriate test for the minimal improvement in purity that will give rise to novelty.

As with many things in the law, determining what level of purity constitutes novelty is ascertained by weighing all the factors in the individual circumstances. Whereas a given increase in the purity of cellulose, which is felted into moderately better paper, may not mark a patentable advance, an equal increase in the purity of aspirin, which allows the product to be used therapeutically, does mark such a patentable advance. Perhaps Hand put it best when he said: "the line between different substances and degrees of the same substance is to be drawn rather from the common usages of men

[92] *Parke-Davis*, 189 F. at 103.

than from the nice considerations of dialectic."[93] Apparently weighing all the circumstances, Judge Haynsworth found that the improved purity in the vitamin B-12 was worthy of patent protection.

A more difficult problem arises when the increase in purity leads to improved function, but the use remains the same. Suppose that, in the aspirin case, the original aspirin was therapeutically effective. Would an increase in its purity have constituted a patentable advance? The new drug would have no new use, but assume that it is much more effective, and that there are many fewer side effects, which are associated with the drug's impurities. Does this make the new product novel? On the one hand, we want to encourage the development of the highest quality pharmaceuticals, including more precise targeting of disease. On the other hand, we do not want to discourage investors from funding new pharmaceutical research for fear of inadequate patent protection. There appears to be no easy solution to this problem; it lies directly within the murky area of the purity spectrum, precisely where Hand would say that a difference in degree becomes a difference in kind.

Rent dissipation theory presents an interesting lens through which to view the economic interests at stake in legal decisions regarding novelty by purity. Rent dissipation theory has arisen from the more traditional economic theory of rewards, which attempts to explain the economic purpose of granting patents in the first place.

[93] *Id*.

Although monopolies, in general, are bad for the economy, reward theory posits that a temporary monopoly is a good way to reward the inventor's risk and expense. Otherwise, the reward to inventors would be too small to justify taking the risk of investing in the uncertain financial arena of technical innovation, especially considering that competition would ultimately drive down prices to the extent that the original inventor would have a difficult time retrieving his initial investment, let alone a return on his investment.[94] The problem is that in practice, patents tend to be too broad or too narrow to be economically efficient.[95] The narrower the protection, the greater the danger that a third party will develop a relatively small but non-infringing improvement, thereafter appropriating virtually all of the rent from the inventor's original invention. A patent system like this would "punish the bold and reward the fussy."[96] The broader the protection, the more likely that an aspiring improver will be discouraged from improving, and the more society will suffer a deadweight loss.[97]

Rent dissipation theory takes as its starting point the assumption that society profits from innovation, and that the proper measurement of this profit is the difference between what society would pay for the innovation and its actual cost.[98] This societal

[94] Erramouspe, *supra* note 8, at 985.

[95] Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 Va. L. Rev. 305, 307 (1992).

[96] *Id.*

[97] *Id.*

[98] *Id.* at 308.

profit, the rent, is to be awarded to the inventor through the patent system. One problem with this system is that the rent is often quite large, which inevitably leads to a situation which is in many ways like a gold rush: numerous competitors compete for the ultimate prize.[99] The costs associated with these redundant development efforts dissipate the benefit to society. The theory further predicts that an analogous societal loss will be suffered if potential inventors race to make patentable improvements on a pre-existing invention.[100] Thus, if the invention signals any conceivable means for improvement, another gold rush will ensue.

If the courts uphold patents for improvements in purity too loosely, without requiring a considerable advancement in utility, then society will suffer a monstrous deadweight loss. Not only would society lose when inventors compete over the rights to the original invention, but it would further lose when the prospective inventors expend large quantities of capital in search of relatively worthless purification. This suggests that the primary consideration in determining whether an enhancement in purity amounts to novelty should be the economic utility of the advancement. In other words, the level of purity that should be required to surpass the scope of the original patent should be sufficiently high to avoid giving prospective inventors an incentive to dissipate society's profit, while at the same time low enough to encourage improvements which will increase the overall benefit to society.

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[99] *Id.*

[100] *Id.*

The recombinant DNA industry is one area in which purity considerations are of utmost importance. It has been stated that the development of biotherapeutics can be divided into four distinct phases: initial observations, determination of genetic structure, large-scale production, and clinical testing.[101] During phase I, the protein or other biological factor is isolated and purified; during phase II, the genetic sequence is determined.[102] After *Parke-Davis*, courts have upheld product patents filed during phase I, no matter how much better the subsequent processes developed during phase II may be.

Consider the 1991 Federal Circuit case involving Scripps Clinic and Genentech.[103] In that case, Genentech developed a new process for obtaining purified Human Factor VIII:C, a complex protein associated with blood clotting and used to treat hemophilia. Before the invention, researchers had succeeded in isolating the Factor VIII:C in plasma. However, the process was inordinately expensive because a large volume of whole blood was needed as starting material. In addition, there was a significant possibility of contamination and disease resulting from impurities in the source blood, not to mention the large volume of concentrate that still had to be administered to the patient. The process that the patentee came up with was essentially a chromatographic absorption of the Factor VIII:C complex using monoclonal antibodies

[101] Sanzo, *supra* note 4, at 394.

[102] *Id.* at 395.

[103] *Scripps Clinic & Research Found. v. Genentech, Inc.,* 927 F.2d 1565 (Fed. Cir. 1991).

specific to Factor VIII:RP, a related protein that contaminated the sample, followed by the separation of the Factor VIII:C.[104]

The Court upheld the earlier product patent on Factor VIII:C, finding Genentech's production to be an infringement, in spite of the substantially improved process that Genentech had developed, leading to what some have described as "unfortunate social policy."[105] It is unfortunate because it operates to inhibit technical advance in biotechnology, where much invention involves improving the way in which purified natural products are produced.[106] The natural solution would be to avoid granting product patents, which are generally of unnecessarily wide scope, in favor of granting process patents, which are better fitted to the scope of the inventor's contribution.[107]

Another problem that arises in finding novelty by purity is the way in which the original inventor claims his invention. In *In re Fisher*,[108] the patentee developed a new process to obtain adrenocorticotrophic hormone, abbreviated ACTH. Fisher's product was significantly more pure than anything in the prior art, and was the first ACTH to be available as a treatment for humans. The problem with the products in the prior art was that when the ACTH was extracted from the animal pituitary glands, there remained

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[104] *Id.* at 1568-69.

[105] Merges & Nelson, *supra* note 71, at 904.

[106] *Id.*

[107] *Id.* at 914.

[108] *In re Joseph D. Fisher*, 307 F.2d 948 (C.C.P.A. 1962).

"certain undesirable factors which are tolerated only in very limited amounts by the human being."[109] The impurities in the prior art, consisting essentially of posterior pituitary factors containing oxytocic and vasopressor activity, caused patients to have serious side effects. Fisher conceded that ACTH was well understood before his work, but insisted that his pure product was a novel substance. The claim at issue read:

> An adrenocorticotrophic hormone concentrate having a potency at least equal to that of the International Standard, said concentrate having a posterior pituitary contamination at least as low as 0.08 unit of vasopressin activity per International unit of adrenocorticotrophic potency.[110]

The Court reasoned that since Fisher was required by 35 U.S.C. § 112 to construct his claims in a way "particularly pointing out and distinctly claiming the subject matter which [he] regards as his invention,"[111] to uphold his patent, the novelty of his invention must be adequately pointed out in his claim. Fisher relied solely on the particular minimum potency and the particular maximum contamination of his product to establish this novelty.[112] The Court concluded that Fisher's claim was an "expression of what [his] concentrate will do rather than what it is."[113] Potency speaks to the product's ability to effect a result, not to what the product actually is. The same is true of vasopressin activity. The Court invalidated the patent without more. It is apposite to note that the

[109] *Id.* at 949.

[110] *Id.* at 950.

[111] 35 U.S.C. § 112 (2001).

[112] *In re Fisher*, 307 F.2d at 951.

[113] *Id.*

Court never suggested that Fisher's work lacked novelty; rather, it held only that Fisher's claim used "conveniently functional language at the exact point of novelty,"[114] thereby failing to meet the enablement requirement of 35 U.S.C. § 112.

Fisher relied on numerous cases, including *Parke-Davis*, to establish that a patent claiming a purified form of a pre-existing product is valid. The Court agreed, clarifying that it was not the subject matter but the form of the claims that was the problem. Fisher attempted to use *Merck* as authority for the proposition that a patent is valid even if it uses functional language in its claim. The claim in *Merck* read as follows:

> A vitamin B-12 active composition comprising recovered elaboration products of the fermenatation of a vitamin B-12 activity producing strain of Fungi . . . the L.L.D activity of said composition being at least 440 L.L.D. units per milligram and less than 11 million L.L.D. units per milligram.[115]

The Court examined the reasoning behind allowing this claim and concluded, although conceivably running counter to the authority of the wood paper patent case, that much of the invention's novelty was derived from the fact that the production of vitamin B-12 was derived from an entirely different source than the vitamin B-12 in the prior art.[116] Fisher's ACTH was derived from exactly the same source as in the prior art, and therefore lacked novelty.

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[114] *Id.*

[115] *Merck*, 253 F.2d at 157.

[116] *In re Fisher*, 307 F.2d at 954.

*In re Fisher* demonstrates that in addition to needing a level of purity that amounts to a distinction in kind, the claims must adequately reflect this distinction in order to achieve novelty. However, in so doing, the Court ironically makes it more difficult for inventors to protect themselves from "design-around" companies by prohibiting the inventors from claiming their inventions by specifying the range of purity that they believe constitutes their contribution to the art. This is an interesting problem. No doubt Fisher intended to claim his invention with as much particularity as possible, listing the specific ranges of potency and purity that he believed he had developed. Yet, the Court insisted that he not claim the product based upon its activity. Therefore, depending on how difficult it is to convert the activity ranges into ranges precisely describing the proportions of the materials constituting the product, the Court's position becomes, in the best case, a mere formality, and in the worst case, an insurmountable bar to the patenting of a purified product.

## VIII. Conclusion

While every court agrees that a product of nature is not a patentable invention, it is curious that no court has come up with a satisfactory definition of what a product of nature actually is. Great confusion envelops the case law dealing with this subject, most likely caused by the lack of a well-accepted statutory basis for the doctrine. While § 101 is an obvious contender, modern cases have reduced its clout to the extent that it is doubtful whether § 101 has any bite left at all. A potential solution to this problem is to

find constitutional authority for the products of nature doctrine as a corollary to the constitutional principle of an inviolable public domain.

Notwithstanding the ambiguity surrounding the source of the products of nature doctrine, the fact remains that it is well accepted and deeply rooted in the patent law. Learned Hand's opinion in *Parke-Davis* carved out an exception to the doctrine, allowing for purified natural products with therapeutic properties to merit patent protection. Considering that the result in *Parke-Davis* is far from intuitive, it is extremely surprising that it was so well incorporated into the law. No case has ever held against its authority. Perhaps this is because the result in *Parke-Davis* does not go visibly against the grain of the patent system as a whole. It can be defended if one embraces an economic ideology, justifying the need to reward those who undertake socially beneficial endeavors that are both expensive and risky.

The problem with such an economic argument is that its logic is not limited to the biotechnology industry. If the purification exception is compelling, it is because products in the biotechnology industry are expensive to develop due to the high fixed cost of research and development. But if that is so, then why are equally expensive endeavors in different scientific industries, such as creation of purified tungsten, ductile vanadium, or the purified fissile isotope of uranium, not likewise patentable? Certainly it cannot be because it is easier for courts to come to the conclusion that purified tungsten is natural, but purified adrenaline is not. Such a conclusion is unfounded in logic; both exist in nature in an impure form, and both require the ingenuity of man to isolate and purify.

The disparate treatment of the scientific industries greatly reduces the force of the economic argument.

The only justification for this disparity is that courts have placed high social priority on the development of biotechnology, wishing to extend greater legal protection to those who endeavor to expand that industry. Perhaps this is reasonable, but why is there no mention of this policy goal in any of the case law dealing with the subject? It seems more likely that Learned Hand simply confused the subtleties of the prior case law, believing that the result in *Parke-Davis* was prescribed by law and not an innovation of his own making. There was no discussion of natural products in *Parke-Davis* at all. Hand borrowed a doctrine finding novelty by purity from cases dealing with man-made products, most probably without even realizing the distinction. However, finding novelty by purity is inherently linked to § 102, and is therefore conceptually unrelated to the unpatentability of a product of nature. Thus, from a formalist's viewpoint, the result in *Parke-Davis* is indefensible. Nevertheless, as it stands today, it is the law.