

Isolated DNA and the “hand of man”.

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New *Prometheus/Myriad* guidance appeared on the USPTO website on 4 March under the title *2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature\Natural Principles, Natural Phenomena, And/ Or Natural Products*². The purpose of this paper is to provide comments in advance of a forum to be held at the USPTO on 9 May 2014. An alternative approach is advocated and reasons for preferring that approach are advanced.

The approach to interpretation

The task of a court in interpreting §101 is explained in the following passage from *Diamond v Chakrabarty*³:

“Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done, our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U.S.C. § 2181(a), exempting from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is.”

The task of the USPTO in interpreting the *Mayo* and *Myriad* decisions is similarly narrow. It is limited to making of a correct determination from those decisions of the rule(s) of law applied by the Court and then making a corresponding adjustment to examination practice (if needed). Either under-stating such rules and making too limited adjustments or gold-plating such rules and making unduly far-reaching adjustments strays outside the metes and bounds of that task.

It is submitted that the second paragraph of the Memorandum over-states the need for a new procedure concerning application of the law relating to natural products. The view as to what amounts to a

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² http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf

³ 447 U.S. 303 (1980)

significant difference from what exists in nature is unduly demanding, and it is not apparent that any meaningful change in the law and practice relating to chemicals derived from natural sources, proteins or peptides and other substances found in nature is required. For all these materials the correct legal test, as explained below continues to be the long-established test of novelty (including novelty of form, concentration or purity) and new utility carried forward from many long-established decisions and approved in *Chakrabarty*. As regards nucleic acids, as discussed below, it is strongly arguable that as a minimum position isolation as a molecular species obtained *in vitro* rather than predicted *in silico* and definition by by a molecular formula (nucleotide sequence listing) and credible new utility should suffice for patent-eligibility.

***Chakrabarty* and the difference + new utility test**

The Office continues to rely on *Chakrabarty* as `central to the eligibility enquiry. In that decision the Court made the following findings:

Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity "having a distinctive name, character [and] use." *Hartranft v. Wiegmann*, [121 U. S. 609](#), [121 U. S. 615](#) (1887). The point is underscored dramatically by comparison of the invention here with that in *Funk*.... Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

The *Hartranft* case (also cited in *Myriad*) concerns liability to import duty rather than patents, but is nevertheless illustrative. At issue was whether ornamental shells that had been cleaned to remove the epidermis and then polished on an emery wheel to expose the pearly interior were products of nature or manufactured articles. The Supreme Court held that the application of labour to an article either by hand or by machine did not necessarily make that article a manufactured article within the meaning of the tariff laws. Blocks of marble cut to convenient size for transport were not regarded as manufactured. Washing and scouring wool did not make the resulting wool a

manufacture of wool. Cleaning and ginning cotton did not make the resulting cotton a manufacture of cotton. Hay pressed into bales, ready for market, was not a manufactured article, though labor had been bestowed in cutting and drying the grass and baling the hay. Even round copper plates turned up and raised at the edges from four to five inches by the application of labor to fit them for subsequent use in the manufacture of copper vessels, but which were still bought by the pound as copper for use in making copper vessels, were held not to be manufactured copper. However, India-rubber shoes, made in Brazil by simply allowing the sap of the India-rubber tree to harden upon a mould, were a manufactured article because it was capable of use in that shape as a shoe, and had been put into a new form capable of use and designed to be used in such new form. The present shells were not manufactured articles because they were still shells and had not been manufactured into a new and different article having a distinctive name, character, or use from that of a shell. The dividing line *in Hartranft* is a change in form accompanied by a new function or utility which appears to be the key requirement.

On page 5 the Guidance suggests that the relevant question is whether something that initially appears to be a natural product is in fact non-naturally occurring *and* markedly different from what exists in nature, i.e., from naturally occurring products. This question can be resolved, the Guidance suggests, by first identifying the differences between the recited product and naturally occurring products, and then evaluating whether the identified differences together rise to the level of a marked difference in *structure*. It is not apparent that this formulation is consistent with the findings in *Chakrabarty* where novelty is acknowledged and the phrase “markedly different” is used in relation to characteristics. In the case of a microorganism are could include behavioural features, as in the *Chakrabarty* specification itself⁴ where growth rates were used as characteristics from which the presence of a given degradative pathway could be inferred⁵.

The Court noted in *Chakrabarty* that the Office had before the 1970 *Plant Variety Protection Act* issued patents for bacteria and quoted⁶ the granted claim in an 1873 patent of Louis Pasteur⁷. The problem with which he was concerned was changes in the condition of brewers’ yeast, worts and beer and limitations on these keeping beyond a certain time. He concluded that these problems arose from microorganisms

⁴ US 4259444

⁵ The quoted passage is the only instance where the language “marked difference” appears in *Chakrabarty*.

⁶ *Chakrabarty*, footnote 9.

⁷ US 141072 issued 22 July 1873.

that contaminated the yeast, devised a procedure that would eliminate these contaminants, and as noted by the Court claimed:

“Yeast, free from organic germs of disease, as an article of manufacture.”

It will be apparent that the difference that the Court was willing to accept went beyond a change in structure and included a change in form or purity, in this case freedom from harmful contaminant, and that the marked difference in characteristics was in the properties that the purified yeast, imparted to beer namely that the beer was not adversely affected and had a longer shelf life.

Freedom from contamination was also held to be a change in form that also supported patentability in *Kuehmsted v Farbenfabriken of Elberfeld Co.*⁸ where acetylsalicylic acid (aspirin) was previously known but only in an impure form. The Court affirmed patentability for pure aspirin as follows:

“Hoffmann has produced a medicine indisputably beneficial to mankind – something new in a useful art, such as our patent policy was intended to promote. Kraut and his contemporaries, on the other hand, had produced only, at best, a chemical compound in an impure state. And 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 Hoffmann and Kraut 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. In the one case the mass is made to yield something to the useful arts; in the other case what is yielded is chiefly interesting as a fact in chemical learning.”

Isolation of a natural product to give a new form with new properties has held to give rise to patentable subject-matter. In 1900 Dr Jokichi Takamine succeeded in isolating and purifying adrenalin in fine crystalline form from the adrenal glands of sheep and oxen, for which he was granted a US Patent⁹. The new product was said to be storage stable when dry and when injected into an animal to bring about a rise

⁸ 179 F. 701, 1910, 7th Circuit

⁹ US 730176, June 2013

in blood pressure. A number of product claims were granted of which the following is representative:

“A substance possessing the herein described physiological characteristics and reactions of the suprarenal glands, having approximately the formula $C_{10}H_{15}NO_3$ and having an alkaline reaction.”

Patentability of adrenalin was affirmed by Judge Learned Hand in a paradigm-defining ruling in *Parke-Davis & Co. v. H.K. Mulford Co*¹⁰ as follows:

“[E]ven if [Adrenalin] 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. That was a good ground for a patent.”

It goes without saying that adrenaline continues in medical use to this day, and sufferers from a range of conditions including notably peanut and similar allergies owe their lives to Dr Takamine’s invention.

Isolation or purification of a naturally occurring substance leading to a non-natural composition of matter with desirable new properties has provided basis for patent grant for over a century in the US and continues to provide such basis in the UK, before the EPO and before the patent offices of substantially every country in the industrialised world. What is remarkable about the *Parke-Davis* opinion is how seldom it has been challenged in the century since it was handed down notwithstanding the multiplicity of patents for naturally-occurring products of great utility and commercial value that have been granted during that time, and how widely the same logic has been adopted in other countries. It is submitted that this long standing line of authority and established practice, implicitly approved in *Chakrabarty* can only be overruled by clear language, and that such language is found neither in *Mayo* nor in *Myriad*.

¹⁰ 189 F. 95, 103 (C.C.S.D.N.Y. 1911)

Myriad

The *Myriad* decision of the Supreme Court sought to reconcile a divergence of opinion in the Federal Circuit concerning the patentability of full-length genes, e.g. the BRCA1 gene. In their briefs Myriad argued that isolation required separation of the specific DNA of interest from the rest of the DNA in the body and even from the rest of the fragmented DNA that may be present in a test tube outside the body. They further argued that the specific isolated BRCA1 and BRCA2 molecules, once defined, are either separated from surrounding genomic and cellular matter at precise locations chosen by the Myriad inventors or assembled in a laboratory in the case of cDNA. Unfortunately for Myriad this argument was counter-factual: isolation of the wild-type BRCA1 DNA as a free-standing molecule had not been described in the relevant specification and there was no disclosure of methods for cleaving it at precise locations of choice. The wild-type BRCA1 sequence listing included the exons but only some 27,000 of the 81,000 bases in the gene.

In the Federal Circuit, Judge Lourie was of the view that patent-eligibility should be considered from the standpoint of a chemist, and that a covalent bond was the defining boundary between one molecule and another. Such considerations were not persuasive to Judges Moore and Bryson, and Judge Bryson explained that:

“If we are to apply the conventional nomenclature of any field to determine whether Myriad’s isolated DNA claims are “new,” it would seem to make more sense to look to genetics, which provides the language of the claims, than to chemistry. Aside from Myriad’s cDNA claims, its composition claims are not defined by any particular chemical formula. For example, claim 1 of the ’282 patent covers all isolated DNAs coding for the BRCA1 protein, with the protein being defined by the amino acid sequence encoded by the naturally occurring BRCA1 gene.”

In the Supreme Court Justice Thomas approved that reasoning in the following language which also draws attention to the absence of sequence information and that the focus should be on genetics, not chemistry:

“Nor are Myriad’s claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule.

Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes."

In his dissent, Judge Bryson relied on *Chakrabarty* and held that as between what is claimed and what is found in nature the focus should be firstly on the similarity in structure and secondly on the similarity in utility. His analysis, which continued to be from the standpoint of a geneticist rather than a chemist, emphasized the absence of any new utility for the isolated wild-type BRCA1 gene and was as follows:

"The structural differences between the claimed "isolated" genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form. *The use to which the genetic material can be put, i.e., determining its sequence in a clinical setting, is not a new use; it is only a consequence of possession.* In order to sequence an isolated gene, each gene must function in the same manner in the laboratory as it does in the human body. Indeed, that *identity of function in the isolated gene is the key to its value.* The naturally occurring genetic material thus has not been altered in a way that would matter under the standard set forth in *Chakrabarty*. For that reason, the isolation of the naturally occurring genetic material does not make the claims to the isolated BRCA genes patent-eligible." (Emphasis added)

Justice Thomas agreed that *Chakrabarty* was central to the enquiry, and that qualifying subject-matter had to be a product of human ingenuity having a distinctive name, character and use. In relation to the wild-state gene Myriad had not created anything. Genes and the information that they encode are not patent-eligible under §101 simply because they have been isolated from the surrounding genetic material.

There is therefore nothing in *Myriad* that modifies or over-rules the difference + new utility analysis in *Chakrabarty* and in the earlier decisions cited above.

The limited and cautious language used in the opinion of Justice Thomas in *Myriad* is a striking feature. In opening he explained that:

“For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible *merely* because it has been isolated...”

At the end of the opinion he summarised the Court’s finding in his concluding remark that:

“We *merely* hold that genes and the information they encode are not patent eligible under §101 *simply* because they have been isolated from the surrounding genetic material.”

It follows that *Myriad* provides authority for the proposition that a DNA sequence that has merely been isolated and has no new utility but only that utility which is a consequence of its possession is not patent-eligible.

Myriad does not provide authority for the proposition that a sequence that has not only been isolated but also has new utility is not patent-eligible: e.g. that a naturally-occurring DNA sequence e.g. of length ~5000 kb that has been isolated or is enabled to be isolated e.g. from a prokaryote as a real physical molecule and that has new utility insofar as it can be multiplied by PCR and incorporated into other organisms that can subsequently be cultured to produce new and valuable medicaments or other chemical species is not patent-eligible. Such a fact pattern was not before the Court in *Myriad* and differs in fundamentals from the fact pattern that the Court was called on to consider.

Nor does *Myriad* provide authority for the proposition that new chemical species, e.g. the macrolide antibiotic rapamycin, which have been extracted from the environment and provided in new and concentrated form are patent-ineligible. There is nothing in either the language or the surrounding fact pattern in *Myriad* to support such propositions and they are contrary to the cautious language in the *Myriad* opinion itself, to the reasoning in *Chakrabarty* and to earlier authority.

Patent eligibility based on purification or isolation and new utility would minimise the problem expressed by Justice Ginsburg during oral argument in *Myriad* that the US was at risk of being placed in a singular position compared to other industrialised nations. Under

the European Biotechnology Directive¹¹ biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. However, it is an essential condition for grant of a patent for a genetic sequence is that industrial applicability should be disclosed in the application as filed. It has been held that under a.57 EPC it is necessary to disclose in definite technical terms the purpose of an invention and how it can be used in industry to solve a given technical problem¹², this being the actual benefit or advantage of the invention. In *Human Genome Sciences*¹³ the principles adopted by the EPO Appeal Boards were reviewed by the Supreme Court (UK) which held that a patent must disclose “a practical application” and “some profitable use” for the claimed substance, and that a merely speculative statement of use would not suffice. Merely identifying the structure of a protein, without attributing to it a clear role, or suggesting any practical use for it was not enough. The words “merely” and “simply” in *Myriad* leave room for development of US law along analogous lines to those under the EPC and point away from a bright line rule prohibiting patent-eligibility of all naturally occurring sequences.

Mayo

Despite the length of the opinion of Justice Breyer, the underlying factual matrix and the reasons for the decision are simple.

The claim in issue read:

¹¹ DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions, [1998] OJL 175/1. In Case C-428/08 *Monsanto* the ECJ pointed out that Article 1(1) of the Directive requires member states to protect biotechnological inventions under their national patent laws and to make adjustments in accordance with the provisions of the Directive. Accordingly the harmonization effected by Article 9 of the Directive (which refers to scope) should be regarded as exhaustive and precludes national legislation from producing a different effect. It will be apparent that the same argument is equally applicable to Articles 3 and 5 and is consistent with the ruling in the *Kingdom of the Netherlands* case C-377/98. The EPO incorporated the provisions of Articles 3 and 5 of the Directive into the Implementing Regulations to the EPC without modification as EPC 2000 rules 27 and 29. These rules now provide legislative authority for the patent-eligibility of claims covering naturally occurring gene under the EPC, and that the resulting patents can be brought into effect in all EPC contracting states, see e.g. T 272/95 *Relaxin/HOWARD FLOREY INSTITUTE*.

¹² T 0898/05 *Hematopoietic receptor/ZYMOGENETICS*.

¹³ [2011] UKSC 51; see also T 0018/09 *Neurokine/HUMAN GENOME SCIENCES*

“A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.”

The method of analysis had been described in a published paper by the inventors¹⁴ whose final paragraph read:

“Our recent preliminary investigative efforts to measure 6-TG in leucocytes have shown a correlation between neutrophil 6-TG levels and responsiveness to treatment as well as drug induced leucopenia. Further research is needed to identify a therapeutic regimen for 6-MP treatment allowing clinicians to establish a balance between drug responsiveness and toxicity.”

It is difficult to avoid the conclusion that what found its way into the patents in issue were the results of the very research that had been recommended in the 1996 paper and which Prometheus had been prompted to under-write. The more natural objection which, unfortunately, was not pursued was therefore lack of inventive step under 35 USC §103. From the standpoint of eligibility, however, the only new subject-matter in the claim concerned levels of the 6-thioguanine metabolite and the significance attaching to those levels. The additional subject-matter did not amount to a method step but was pure information about the behaviour and effects of the drug, at most specifying a need for action without going so far as to include the step of positively taking that action or indeed any further step.

¹⁴ Cuffari, Théorêt, Latour, & Seidman, 6-Mercaptopurine Metabolism in Crohn's Disease: Correlation with Efficacy and Toxicity, *39 Gut* 401 (1996).

Against this background it is not surprising that the cases considered most directly on point were *Diebr* and *Flook*, the case for patentability being weaker than the (patent-eligible) claim in *Diebr* and no stronger than the (unpatentable) claim in *Flook*. The Court considered that more than nominal post-solution activity was needed, citing the English case in *Neilson v. Harford*¹⁵ as an example of qualifying post-solution activity.

It is difficult to identify any new rule of law from *Mayo*. In summarising its conclusions the Court recognised that monetary incentives that lead to creation, invention and discovery must be balanced against raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements, and that:

“At the same time, patent law’s general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U. S. C. §§161–164 (special rules for plant patents).”

It will be apparent that the abundance of cautious language in Justice Breyer’s opinion points away from any dramatic and wide-ranging change in legal principle.

The Examples

The following comments are provided in relation to the examples:

A. The isolated plasmid has novelty insofar as it is removed from its natural environment. The important question is whether it has any new utility going beyond what is implicit in mere possession. Applying the *Hartranft* test it is a new thing having a distinctive name (a plasmid

¹⁵ (1841) 151 ER 1266 (HL). The patented subject-matter concerned one of the most significant breakthroughs in the industrial revolution, leading to significant fuel savings in the operation of blast furnaces.

which is a discrete molecule, not a cell), a distinctive character (it is a small replicatable DNA structure, the DNA having the form of a ring) and new use (it can be inserted into new organisms to create new metabolic pathways within them).

B. Purified amazonic acid is novel since it has been removed from its natural environment and is provided in concentrated form. It self-evidently passes the *Hartranft* test since it has a distinctive new name, a new character being a pure chemical substance rather than a material contained within plant leaves and a new or enhanced utility because it provides a practical cancer treatment whereas the leaves do not. There is nothing in *Mayo* or *Myriad* that should disturb the finding in *Parke-Davis* that such inventions are patentable.

Support from that position can further be derived from the oral argument in *Myriad* which relates essentially to the scenario set out by the USPTO but points towards the opposite conclusion:

“JUSTICE ALITO: Can I take you back to Justice Ginsburg's question, because I'm not sure you got at what troubles me about that. Suppose there is a substance, a chemical, a molecule in the leaf - the leaves of a plant that grows in the Amazon, and it's discovered that this has tremendous medicinal purposes. Let's say it treats breast cancer. A new discovery, a new way is found, previously unknown, to extract that. You make a drug out of that. Your answer is that cannot be patented; it's not eligible for patenting, because the chemical composition of the drug is the same as the chemical that exists in the leaves of the plant.

MR. HANSEN [for the Association for Molecular Pathology and other petitioners]: If there is no alteration, if we simply pick the leaf off of the tree and swallow it and it has some additional value, then I think it is not patentable. You might be able to get a method patent on it, you might be able to get a use patent on it, but you can't get a composition patent.

JUSTICE ALITO: But you keep making the hypotheticals easier than they're intended to be. It's not just the case of taking the leaf off the tree and chewing it. Let's say if you do that, you'd have to eat a whole forest to get the value of this. But it's extracted and reduced to a concentrated form. That's not patent -- that's not eligible?

MR. HANSEN: No, that may well be eligible, because you have now taken what was in nature and you've transformed it in two ways. First of all, you've made it substantially more concentrated than it was in nature; and second, you've given it a function. If it doesn't work in the diluted form but does work in a concentrated form, you've given it a new function. And by both changing its nature and by giving it a new function, you may well have patent ...”

The Guidance cannot be supported if it takes as a rule of law a position that was expressly conceded in oral argument where that concession remains uncontradicted in the resulting opinion.

C. Gunpowder is a mixture of sulphur, charcoal and potassium nitrate (saltpetre). Sulphur and saltpetre occur naturally but charcoal is not a naturally-occurring substance and is made by the slow pyrolysis of wood in kilns in the absence of oxygen. The hand of man further intervenes (a) in selecting the proportions in which the ingredients are mixed, (b) in finely dividing each ingredient, and (c) in intimately mixing the ingredients. Juxtaposed sacks of sulphur, saltpetre and charcoal have no explosive properties: it is the three steps mentioned above that give rise to a material that deflagrates at sub-sonic speeds and provides the well-known explosive and propellant. Although recognition of qualifying subject matter is welcomed the premise of the question is flawed.

D. The example refers to a summary in *Myriad* of the earlier decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co*¹⁶ that “the composition was not patent-eligible because the patent holder did not alter the bacteria in any way.” That proposition implies that the *Funk Brothers* composition could have been eligible e.g. if one or more of the bacterial species had been the subject of a breeding programme so as to produce a strain with markedly different properties from any naturally-occurring strain, but that selection from amongst existing naturally-occurring strains to produce a mixed inoculant having new and valuable properties would not suffice. It is not clear why the achievement of new and valuable utility by the selection from amongst existing bacterial strains to produce a new mixture should be rejected since selection is equally a process of intervention by the hand of man and the resulting mixture does not occur in nature. The *Funk Brothers* product, applying the test in *Hartranft*, had a new name (multi-strain leguminous

¹⁶ 333 U.S. 127, 131 (1948)

inoculant) with a distinctive character (the strains were non-inhibitive) and use (application to any leguminous plant needing inoculant).

Justice Douglas's analysis, quoted in the Guidance, was that:

“The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had.”

Regrettably that analysis is factually wrong on the face of the opinion. The inventor Bond indeed changed the six species of bacteria by the process of selecting mutually non-inhibitive strains and by combining the selected strains. The range of their utility was indeed enlarged by the ability of the selected strains to be packaged together and to be effective for the inoculation of a wide range of leguminous plants. But in any event the opinion of Justice Douglas remains consistent with the novelty and utility test.

Justice Frankfurter expressed concern that the Court's opinion should not be given an unduly wide interpretation:

“It only confuses the issue, however, to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent. On the other hand, the suggestion that, "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" may readily validate Bond's claim. Nor can it be contended that there was no invention because the composite has no new properties other than its ingredients in isolation. Bond's mixture does, in fact, have the new property of multi-service applicability. Multi-purpose tools, multi-valent vaccines, vitamin complex composites are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged. In finding Bond's patent

invalid, I have tried to avoid a formulation which, while it would in fact justify Bond's patent, would lay the basis for denying patentability to a large area within existing patent legislation.” (emphasis added)

The above passage also points to a conflict between the opinion of Justice Douglas and earlier authority. An explanation of the significance of new effect in established patent law can be found as long ago as 1822 in *Evans v Eaton*¹⁷:

“That a new *modus operandi*, by a new combination of old instruments or machines, so as to produce either a new effect, or an old effect in a new way, is the proper subject matter of a patent, appears from numerous authorities, and may be considered as a settled principle of the patent law. It was on this principle that Watt's patent for his improvements on the steam engine, which made so much noise in Westminster Hall, and produced such important effects, was finally supported and established.”

The evidential nature of a new effect was explained in an important statement of principle that appears in the opinion of Justice Bradley in *Webster Loom v Higgins*¹⁸, subsequently approved e.g. by Justice Brown in *Carnegie Steel v Cambria Iron Co.*¹⁹:

“It may be laid down as a general rule, though perhaps not an invariable one, that if a new combination and arrangement of known elements produce a new and beneficial result, never attained before, it is evidence of invention.”

It is apparent from Justice Douglas's opinion that one of his reasons for rejecting that evidence in *Funk Brothers* was the nature of the benefit which he dismissed as “hardly more than an advance in the packaging of innoculants” and as a commercial rather than a technical benefit. It is not clear that this reason was adequate or supported by previous authority.

His opinion was also based on a conclusion that the reference to non-inhibition was of unjustified breadth. That objection was made in more detail in the concurring opinion of Justice Frankfurter, who also

¹⁷ 20 U.S. 356 (1822)

¹⁸ 105 US 580 (1881)

¹⁹ 185 US 402 (1902)

confirmed the principle that novelty + new utility suffices for eligibility and commented:

“Insofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention, and, as such, patentable, I agree, provided not only that a new and useful property results from their combination, but also that the particular strains are identifiable and adequately identified. I do not find that Bond's combination of strains satisfies these requirements. The strains by which Bond secured compatibility are not identified, and are identifiable only by their compatibility.”

The conflict with *Hartranft* has already been noted.

In view of the divided and problematic nature of the *Funk Brothers* opinion and notwithstanding its recent citation in a number of recent Supreme Court opinions, it is suggested that the wiser course would be not to include its fact pattern as an example for forward-looking patent examination procedure.

E. In relation to claim 1, the primers are identified by oligonucleotide sequence, they are isolated molecules having physical existence, their novelty is considered from a chemical rather than a genetic standpoint because they are intended to participate in a PCR reaction, and they have new utility. Commonly they are not derived from natural sources but are made by oligonucleotide synthesis. It would be an oddity if a prohibition relating to products of nature were extended to molecules made by stepwise chemical synthesis and HPLC to ensure purity, whether or not those synthetic molecules are identical to regions within naturally-occurring sequences. In terms of length and selection they are markedly different from anything occurring in nature.

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