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SWEET & MAXWELL
Mayo v Prometheus: No Patents on Conventional Implementations of Natural Principles and Fundamental Truths

Richard H. Stern

The Supreme Court’s unanimous opinion in the Prometheus case restates the US standard for eligibility of patent grants on implementations of natural phenomena and laws of nature, based on precedents going back to the Exchequer’s 1841 Neilson decision. As evolved in US law, the standard requires that such implementations add something to the underlying principle, whether new or old, beyond the obvious, conventional expedients already known to scientists and artisans, and limits claims scope fairly tightly to that which the inventor has taught the public. The Court’s opinion masterfully harmonizes difficult-to-reconcile precedents. But the uncertain limits of what is a natural phenomenon may create troublesome problems for pharmaceutical and biopharmaceutical companies.

In Mayo v Prometheus, the US Supreme Court revisited the question of what kinds of things are eligible to be considered for patenting for the second time in two years, after a 30-year silence. In the court’s 2010 effort, Bilski v Kappos, the court had stumbled, waffled and divided 5:4, moreover, different opinions and different majorities resolved different legal points. As described earlier in this journal, the court’s 2010 Bilski opinion gave little or no forward-looking guidance—guidance beyond the judgment to be rendered in the case at bar:

“In the wake of Bilski the Federal Circuit, the district courts, the patent office, the patent bar and the bar’s business advisors are left in confusion and doubt over the patent-eligibility of business methods, computer software and gene technology. When are they and when aren’t they abstract ideas? … The inconclusive Bilski opinion makes no suggestion. And if the invention implements [an underlying law of nature, abstract idea or mathematical principle], how besides the machine-or-transformation test can anyone determine patent-eligibility? Instead of bringing clarity to this field of law, as had been widely hoped on the basis of much wishful thinking, Bilski promises only a vast amount of further litigation. It is just a damp squib.”

But this time in a more explanatory opinion than Bilski a unanimous court reversed the Federal Circuit’s judgment of patent-eligibility upholding a patent effectively pre-empting a natural principle. The lower court’s opinion had fundamentally rejected the Supreme Court’s decisions of the 1970s—Benson and Flook—as well as much earlier precedents on which those decisions rest. Speaking with a single voice, without dissents or qualifying concurrences, the court overturned the lower court’s expansive approach to patent-eligibility, and ordered a return to the Supreme Court’s earlier doctrines. In doing so, the court for the first time agreed upon a full harmonisation of its prior and at times seemingly inconsistent judgments on patent-eligibility and how to determine it. The skill displayed in the Prometheus opinion’s harmonisation exercise was remarkable because of the considerable difficulty there is in reconciling the disparate doctrines and methodologies that the court has used in deciding the different cases and in the face of one 5:4 decision in which the dissent plausibly claimed that the majority opinion effectively overruled the court’s
The claimed invention is a diagnostic assay. At the harmonisation in *Prometheus* requires some willing suspension of disbelief by the reader or at least a considerable tolerance toward “fancy footwork”. Nonetheless, it works. It works and it is a very high quality piece of legal craftsmanship. Judging it on its technical merits, it may well be the Supreme Court’s finest work in the patent-eligibility field. Nonetheless, some troubling points remain to be resolved.

**The factual background**

The claimed invention is a diagnostic assay. At the relevant time, the use of thiopurine compounds to treat patients with autoimmune diseases, such as Crohn’s disease, was known. It was also known that thiopurines metabolise in the human body to metabolites such as 6-thioguanine and that the levels of these metabolites in the blood were correlated with the likelihoods that dosages of a thiopurine drug could, on the one hand, cause harm because too high or, on the other hand, prove ineffective because too low. It was not known, however, what specific blood levels indicated too high or too low a dosage, and the inventors first made precise findings on that score. They discovered and claimed the “low” dosage level of 230 picomoles of metabolite per 8 x 10^6 red blood cells and the “high” dosage level of 400 picomoles of metabolite per 8 x 10^6 red blood cells. A representative claim of the patent was:

“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 x 10^6 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 x 10^6 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.”

**The ultimate ruling**

The principal challenge to the patent was that it pre-empted use of a law of nature, an empirical principle—the principle that effective medicinal dosages of thiopurine produce a blood level of metabolite in excess of about 230 pmol per 8 x 10^6 red blood cells while dosages producing a blood level over about 400 pmol per 8 x 10^6 red blood cells risk a toxic reaction. The court said that it must be understood that the stated relation itself—a sort of eternal truth—exists in principle apart from any human action:

“The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.”

For a process embodying or implementing a law of nature to be patented the claim to the process must contain more than the law of nature. Purely “conventional or obvious” activity, as this claim contains, the court said, does not transform the claim from one to the natural principle to something more. The normal way to utilise this law of nature is to do exactly what the claim prescribes “and so the combination [of steps] amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.” In a nutshell:

“To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”

The rest of this article discusses how the court supported that conclusion and what some of the implications are.

**The historical precedents**

*Prometheus* is by no means a case of first impression. Its roots go back more than a century and a half to the interaction between the patent system and the Industrial Revolution. The time was one of many scientific discoveries and their implementation into new machines and processes.

**The Neilson case**

*Neilson v Harford* is probably the best place to begin. By 1841 it was accepted that one could not have a patent on an idea. That was the problem that the Exchequer

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11 A pmol or picomole is one trillionth of a mole, which is one gram molecular weight (GMW) of a chemical. One GMW is 6 x 10^12 molecules of the chemical. In grams, the weight in a mole or GMW is the sum of the atomic weights of the molecule’s constituent atoms. Thus the atomic weight of oxygen is 16, that of hydrogen is 1, and the GMW of water, H2O, is therefore 18.

12 It is like a Platonic form or a στοχος (stochos).


14 *Prometheus* 132 S. Ct. 1289, 1298 (2012).

15 *Prometheus* 132 S. Ct. 1289, 1298 (2012).

barons saw in Neilson’s patent. Neilson realised that the internal temperature and fuel efficiency of a blast furnace could be increased to produce better iron, by blowing hot air into the furnace rather than cool air as had previously been customary. He supplied the hot air by passing the air input through an iron box that he heated externally. The defendant-infringer argued that Neilson was impermissibly trying to patent the principle that furnace temperature could be increased by injecting hot air instead of cold air into the furnace. That would have been in violation of the legal doctrine that one could not have a patent on an idea or principle. But the court ruled that Neilson’s patent permissibly covered an apparatus for exploiting the principle, rather the principle itself. Exchequer Baron Parke explained:

“It is very difficult to distinguish it from the specification of a patent for a principle, and this at first created in the minds of the court much difficulty, but after full consideration we think that the plaintiff does not merely claim a principle, but a machine embodying a principle ... We think the case must be considered as if, the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this — by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace.”

The Neilson decision influenced the US Supreme Court in resolving the Morse Telegraph case, a few years later, and has remained a foundation of the law of patent-eligibility. We will need to return to it.

The rationale of Neilson is that the patent is on an apparatus or machinery implementing the natural principle, rather than on the principle itself. The decision does not judge the difficulty or complexity of the implementing device. It does not consider whether the implementation is trivial, once one is in possession of the principle. At first blush, heating a receptacle or its equivalent to get the air hot seems the natural, perhaps the only sensible, way to heat the air. But this is 170 or more years later and perhaps we are in no position to judge that. But the question of triviality in implementation came to the fore in the 20th century and now in Prometheus as well.

The Morse case

As the Supreme Court explained in Morse, the problem that would-be telegraphers faced in the early 19th century was this:

“The great difficulty in their way was the fact that the galvanic current, however strong in the beginning, became gradually weaker as it advanced on the wire; and was not strong enough to produce a mechanical effect, after a certain distance had been traversed.”

To send a signal from Baltimore to Washington would require thousands of volts and high currents—not feasible at a time when managing to make a pickled frog’s legs twitch was thus far the major achievement of the “electro-galvanic force”.

Morse’s “plan for combining two or more electric or galvanic circuits, with independent batteries for the purpose of overcoming the diminished force of electromagnetism in long circuits” is illustrated in Figure 1.
Morse inserted the relays (or “repeaters” as the court’s opinion terms them) at intervals sufficiently short (say, every 10 miles) that the signal was restored regularly to substantially its initial level before the noise could swamp it out. This was Morse’s great invention.

Morse was not satisfied, however, with claiming just the “repeater” telegraph apparatus. He felt that he had invented more broadly, that he deserved a greater monopoly, and therefore he asserted, in his notorious eighth claim:

“I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims, the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer.”

The Supreme Court rejected Morse’s Napoleonic claim—which amounted to one for a monopoly on any method of remotely transmitting intelligible information by using the electromagnetic force, however developed—for example, by radio, television or the internet, none of which Morse could even have imagined. The court pointed out that Morse had not taught the public in his patent any way to send telegraphic messages except with the repeater apparatus and therefore he deserved no greater monopoly:

“In fine, he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore cannot describe when he obtained his patent.”

Furthermore, the court believed that the patent monopoly Morse claimed, by pre-empting the possible patents of other artisans, would discourage their inventive efforts to devise and teach the public other ways to exploit the electromagnetic force for sending messages. Imagine, if you would, the potential inventor of the radio telegraph or internet, if a contemporary of Morse during the term of his patent:

“For ought that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it, without the permission of this patentee.”

Thus granting Morse the broad patent he claimed would hinder, rather than promote, technological progress by getting in the way of other inventors. This concern has remained central in this branch of the law.

The case “most relied on and pressed upon the court in behalf of the patentee” in the argument before the Supreme Court was Neilson: it was claimed on Morse’s behalf that Neilson supported grant of a patent on the principle on which an improved process was based. The Supreme Court denied this, pointing to Baron Parke’s explanation that the principle Neilson discovered—that a hot air blast made better iron than a cold one—was physically embodied in a heated receptacle that implemented the principle so that it could be applied to the patented process. Thus the patent was not on a principle but an apparatus for exploiting the principle: “The interposition of a heated receptacle in any form was the novelty he [Neilson] invented.” To be sure, Neilson did not require any particular “form of the receptacle or the mechanical contrivances for heating it or for passing the current of air through it and into the furnace.” His invention worked with any convenient receptacle. In contrast, Morse’s invention worked only with the “complicated and delicate machinery” that Morse devised, and that was all he taught the public:

26 Morse 56 U.S. (15 How.) 62, 113 (1853). Several justices dissented, however, on the ground that Morse was entitled to claim all telecommunication use of the electromagnetic force because that was what he invented: “If the result of this application be a new and useful art, and if the essence of his invention consists in compelling this hitherto useless element [EMF] to record letters and words at any distance and in many places at the same moment, how can it be said that the claim is for a principle or an abstraction?” Morse at [135].
27 Morse 56 U.S. (15 How.) 62, 113 (1853).
30 Morse 56 U.S. (15 How.) 62, 117 (1853).
Thus the principle of the Neilson case ran against Morse's claim 8, not for it.

**The Funk case**

Fast forward now about a century to the Funk case. Agricultural scientists had long known that species of bacteria belonging to the *Rhizobium* genus had the power to fix nitrogen from the air, acting in co-operation with the roots of leguminous plants (for example, peas, beans, alfalfa and clover). Different *Rhizobium* species so co-operate with different specific plants, but many or most species compete with one another to inhibit or prevent nitrogen fixation. This "antagonism" required agricultural supply firms, such as the plaintiff and defendant, to supply farm stores with multiple packages of "inoculants" for various different crops, which increased distribution and inventory costs. The patentee discovered that some non-inhibitive strains exist, and that they may be isolated and combined to perform satisfactorily their ordinary desirable nitrogen-fixing functions. This made it possible for Funk to market a single package of inoculants comprising, as claimed:

"[A] plurality of selected mutually noninhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in their ability to fix nitrogen in the leguminous plant for which they are specific." The defendant made a similar product; the patentee sued and prevailed in the court of appeals. The Supreme Court reversed, however, holding that the patent impermissibly claimed a principle of nature:

"The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." Thus the principle could not be patented, nor could any trivial implementation of the principle be patented—only an inventive implementation of the principle could be patented. Here, the implementation was to package selected but unchanged natural strains of bacteria in a single container. But that is trivial:

"[O]nce nature's secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step." In the Funk case, the implementation of the natural principle is so trivial that the distance in concept separating the principle and the implementation is so negligible as to be imperceptible. How else are you supposed to market a mixture of different *Rhizobium* strains except to put them into a package and sell them? If doing that supports a patent, the patent is effectively granted on the principle. The patent totally pre-empts the natural principle and for that reason should not stand.

**The Benson case**

The Benson case was the first computer-related patent-eligibility case to come to the Supreme Court and the first in a defining trilogy of late 20th-century patent-eligibility cases. In Benson, Bell Labs brought a test case to probe the patent-eligibility limits for algorithms by proffering a claim to an algorithm for converting numbers in so-called binary-coded decimal (BCD) format to numbers in pure binary format. Binary data is more useful than BCD data in telephone applications, but human input of numbers such as in dialling a phone number is perform in BCD form. Although Bell extensively argued to the Supreme Court that the device had considerable practical utilisation in public switch box exchanges (PBXs) and related telephone equipment, the claims on appeal did not mention PBXs once. The claims had no end-use limitation at all; any use would infringe. Probably, the patent office would have been satisfied at the beginning of the case if a PBX or other equipment limitation had been put into the preamble of the claim, because then the office would have known in what category ("shoe") of prior art to search for purposes of examination. But Bell Labs wanted to test the legal system and so did not specify a field-of-use limitation to narrow the scope of the claim to a particular branch of mechanical

31 Morse 56 U.S. (15 How) 62, 117 (1853).
32 Funk Bros Seed Co v Kane Incubant Co 333 U.S. 127 (1948) (Douglas J.)
33 The bacteria were not changed. They performed in their natural way. Funk 333 U.S. 127, 131 (1948).
34 Funk 333 U.S. 127, 128 n.1 (1948).
35 Funk 333 U.S. 127, 130 (1948).
37 Gottschalk v Benson 409 U.S. 63 (1972) (Douglas J.).
38 In BCD format each digit of a decimal-format number is represented by a four-place binary number; thus nine is represented as 1001.
39 The boxes in which prior art documents were kept for searching were called "shoes" in those days because they looked like shoeboxes.
art. The patent office had no shoes for algorithms as such or for computer programs, so that it had no way to search for the relevant prior art.\textsuperscript{41} That, among other practical difficulties the office laboured under, meant that the patent office could not make a meaningful prior art search to justify allowing a patent. Although the Government pointed that problem out to the court, and the court gave it a nod,\textsuperscript{42} the main legal argument of the government was straight out of the \textit{Morse} case and that was the rationale of the decision. The patent that Bell Labs sought would pre-empt the algorithm and effectively be a patent on the idea.

At a late stage of the appeal, the Government argued to the Supreme Court that it should adopt a rule, later known as the machine-or-transformation test, for determining when a claim was unduly pre-emptive. The Government reviewed the whole body of Supreme Court decisions on patent-eligibility and summarised them in these terms: in some inventions the apparatus is immaterial because the invention is a way to make a transformation of one substance into a different substance, and the identification of the two different physical substances limits the claim sufficiently so that it is not wholly pre-emptive of a natural principle.\textsuperscript{43} But in other cases of implementing a principle (\textit{Morse} is an example) particular apparatus\textsuperscript{44} and end-use limitations are essential to prevent pre-emption of the underlying principle or idea. Thus, in its \textit{Benson} Reply Brief, the Government said that “we submit that the cases follow such a rule—implicitly or explicitly—and that they cannot be rationalized otherwise.”\textsuperscript{45} Although the Government urged the court to declare such a rule to govern patent-eligibility cases, the court refused:

“It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a ‘different state or thing.’ We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.”\textsuperscript{46}

That was not the end of the machine-or-transformation test, however, for without some objective test it is difficult or infeasible to determine whether a claim is so pre-emptive that it monopolises the underlying principle. The problem becomes like distinguishing idea from expression\textsuperscript{47} or deciding what a reasonable person would believe or do in given circumstances. Apart from the machine-or-transformation test, no bright-line test has been proposed for determining whether a claim is so broad that it pre-empt its principle.

\section*{The Flook case}

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The next important case was \textit{Flook},\textsuperscript{48} in which the court assimilated mathematical principles, algorithms and formulae to the laws and principles of nature considered in \textit{Neilson} and \textit{Morse}. The claimed invention was a “method for updating alarm limits” in the Petrochemical industry. An alarm limit is essentially a numerical margin of safety in a chemical process, such as hydrocracking; the margin changes as temperature (or another relevant parameter) within the chemical reactor increases. The claimed invention calls for monitoring the temperature and manipulating the data by repeatedly computing a moving-time average that weights recent data more heavily than older data (sometimes called exponential or geometric smoothing). The court found the case like \textit{Neilson}, for everything in the claimed process was old and conventional except for the use of the formula.\textsuperscript{49} The court assumed that the formula (or the algorithm for calculating it) was new,\textsuperscript{50} but under the \textit{Neilson} doctrine the equation or the formula must be considered as if already

\begin{itemize}
  \item \textsuperscript{41}To search the prior art without being directed to a shoe would be like trying to look up a word in the dictionary without knowing how to spell it.
  \item \textsuperscript{42}The Government cited and the court quoted a report by a Presidential Commission that had said: “The Patent Office now cannot examine applications for programs because of a lack of a classification technique and the requisite search files. Even if these were available, reliable searches would not be feasible or economic because of the tremendous volume of prior art being generated. Without this search, the patenting of programs would be tantamount to mere registration, and the presumption of validity would be all but nonexistent.” \textit{Benson} 409 U.S. 63, 72 (1972).
  \item \textsuperscript{43}One might question this. For example, suppose that the only way to cross-link natural rubber’s polymer chains to hasten (“vulcanise”) the rubber was to heat it to a certain degree in the presence of sulphur (as Goodyear did). Would that not pre-empt the natural principle of vulcanisation? Goodyear patented his process in 1844 (US Patent No. 3644) and the Supreme Court sustained it (but patent-eligibility was not challenged). See \textit{Rubber Co v Goodyear} 76 U.S. (6 Wall.) 788 (1869). \textit{Benson} gives vulcanisation of uncured India rubber and smelting ores into metals as examples of transformations of substances into other substances. See \textit{Benson} 409 U.S. 63, 70–71 (1972).
  \item \textsuperscript{44}A “particular” apparatus is one specifically adapted to the claimed process, not simply a conventional apparatus used for a new purpose. Thus a newly programmed general-purpose computer would not be a particular apparatus. To assert that would be like saying that putting a new piano roll into an old player piano converted the latter into a new and different machine, as the Government said in the \textit{Benson} case when this argument was made. But see \textit{In re Bernhardt} 417 F. 2d 1395 (Ct Cus. & Pat. App. 1969) (usually credited with originating the “new machine” argument).
  \item \textsuperscript{45}Benson 409 U.S. 63, 72 (1972), Government Reply Br. at 9.
  \item \textsuperscript{46}Benson 409 U.S. 63, 72 (1972), Government Reply Br. at 22.
  \item \textsuperscript{47}Judge Learned Hand wrote in 1930: “Nobody has ever been able to fix that boundary, and nobody ever can.” \textit{Nichols v Universal Pictures Corp} 45 F. 2d 119, 121 (2d Cir. 1930). Thirty years later, in his last copyright opinion before his death, he again concluded that no bright-line test could be devised for delineating idea and expression: \textit{Peter Pan Fabrics v Martin Weiner Corp} 274 F. 2d 467 (2d Cir. 1960). He said that the line between them is “of necessity [so] vague” that “no principle can be stated as to when an imitator has gone beyond copying the ‘idea,’ and has borrowed its ‘expression.’ Decisions must therefore inevitably be ‘ad hoc’.” \textit{Peter Pan} at 488.
  \item \textsuperscript{48}Parker v Flook 437 U.S. 584 (1978) (Sweers J.). In a case intervening between \textit{Benson} and \textit{Flook}, the Supreme Court upheld a patent office denial of a patent on a business method. But the Court sustained the rejection on obviousness grounds rather than reach patent-ineligibility. See \textit{Dann v Johnston} 425 U.S. 219 (1976).
  \item \textsuperscript{49}The patent examiner so found and Flook did not contest the ruling. The court added: “Here it is absolutely clear that respondent’s application contains no claim of patentable invention. The chemical processes involved in catalytic conversion of hydrocarbons are well known, as are the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit alarms must be recomputed and readjusted, and the use of computers for ‘automatic monitoring-alarming.’ Respondent’s application simply provides a new and presumably better method for calculating alarm limit values. If we assume that that method was also known, as we must under the reasoning in \textit{Morse}, then respondent’s claim is, in effect, comparable to a claim that the formula 2\textsuperscript{f} can be usefully applied in determining the circumference of a wheel.” Flook 437 U.S. 584, 595 (1978).
  \item \textsuperscript{50}Although not in the record and apparently unknown to the patent office, the use of such smoothing formulae had been published at least a decade earlier, so that too was old. See Robert G. Brown, \textit{Smoothing, Forecasting, and Prediction of Discrete Time Series} (1963). Another source states that exponential smoothing was first suggested by C.C. Holt in 1957. See Paul Goodwin, “The Holt-Winters Approach to Exponential Smoothing: 50 Years Old and Going Strong” (Fall 2010) Foresight 30, http://www.foresight.org/pdf/foresight/foresight19_goodwin.pdf [Accessed June 5, 2012].
\end{itemize}
a part of the prior art. Invention and patent-eligibility must come, if at all, from an inventive implementation of the principle:

“Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.”

The case differed from Benson in that a field-of-use limitation was present, which in principle could have directed the patent officials to a “shoe” to study. But satisfaction with identification of a shoe had long since evaporated. Thus the court rejected the argument that a limitation to the field of hydrocracking petrochemicals sufficed to avoid the rule against patenting principles and made the claim patent-eligible:

“A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.”

Further, the mechanical aspect of Flook’s device was purely conventional and, apart from the formula, it was “conceded” that there was no “other inventive concept in its application”. Flook’s implementation was conventional and uninventive. Therefore it added nothing of substance to human knowledge and did not deserve patent-eligibility. Morse’s telegraph apparatus, for example, was a device of great genius, as was Bell’s telephone.

Analytic dissection in Flook

A central analytic device in the Flook opinion has remained a controversial issue and has been the basis for considerable US patent bar objection to the Prometheus opinion: the analytic dissection of what is claimed to discard inherently patent-ineligible parts before considering the patent-eligibility of the remainder. As Neilson did, Flook puts aside the patent-ineligible principle (the algorithm or formula) and requires patent-eligibility to come, if at all, from the remainder—the implementation of the principle. The alternative approach is to treat the entire claimed subject-matter as “a buzzing blooming confusion” that must somehow be analysed en masse, as a gestalt—which vastly increases the burden to make the claim coherent and to analyse it rationally.

Analytic dissection as a conceptual tool comes from US copyright law, where it is used to distinguish immaterial similarity from the substantial similarity that results in a finding of copyright infringement. In analytic dissection, unprotected elements of a work are dissected out first and discarded before making any comparison of the two works to determine substantial similarity and thus copyright infringement. These unprotected components include idea (as contrasted with expression), scènes à faire (conventional elements typical of a genre), material in the public domain, constraints of the medium and functional aspects. As the Ninth Circuit explained in the Data East case, protecting such aspects of a work “would confer a monopoly of the [underlying] idea upon the copyright owner”. That is, others could not effectively compete with the copyright owner in creating other works of the same general type without using these features, which properly considered therefore are, as the Funk decision puts it, “part of the storehouse of knowledge of all men”. Infringing substantial similarity must be based on the similarity of what remains after the unprotected elements are dissected out, for the unprotected elements are public property.

Although Data East was a video game case, its legal principle has become of wide applicability in copyright law. Shortly after the Ninth Circuit’s decision, other US courts began to use analytic dissection to determine whether computer programs infringed one another. The test has since become the “gold standard” test of copyright infringement in US computer software cases. Analytic dissection is widely applied in copyright law “to the extent that it is recognised in the USA, and elsewhere, as the accepted standard”.

The use of analytic dissection in patent law to determine patent-eligibility, however, has been controversial. The Federal Circuit and patent bar have opposed its use on the ground that it makes it too easy to reduce any invention to its unprotected constituents and thus invalidate the patent. Instead, it is argued, claims should be “considered as a whole”. The fallacy of that argument, however, is that the patent statute does not

52 The field-of-use limitation kept the claim from wholly preempting the use of the algorithm or formula. But if there are five fields of use, and each is separately patented, the collective pre-emption would be total. A field-of-use limitation in any one patent would thus be ineffective in preventing total pre-emption.
54 Flook 437 U.S. 584, 594 (1978). See also Flook at [595], quoted in fn.49 above.
55 The Supreme Court recognised that Morse’s apparatus contained “complicated and delicate machinery, adjusted and arranged upon philosophical principles, and prepared by the highest mechanical skill”: Morse 56 U.S. (1 How.) 62, 117 (1853).
56 Data East USA, Inc v Epyx, Inc 862 F. 2d 204, 208 (9th Cir. 1988) (collecting authorities).
57 See Data East 862 F. 2d 204, 208 (9th Cir. 1988) (“To determine whether similarities result from unprotected expression, analytic dissection of similarities may be performed in expression arise from use of common ideas, then no substantial similarity can be found”).
58 See Computer Associates Int’l, Inc v Altai, Inc 982 F. 2d 693 (2d Cir. 1993); see also Gates Rubber Co v Bando Chemical Industries, Ltd 9 F. 3d 823 (10th Cir. 1993).
59 The term “abstraction-filtration-comparison” test is frequently used to describe analytic dissection in computer software cases because those are the successive stages of analysis.
require patent-eligibility to be determined by considering the claim “as a whole”. That is an express requirement of § 103, which makes it a condition of patentability that the claimed subject-matter considered as a whole not be obvious over the prior art. No such language occurs in § 101, which governs patent-eligibility. And the customary rule of statutory construction is that such a difference in wording between two sections of the same statute creates a presumption of an intended difference in meaning. It should therefore be presumed that Congress did not desire any gestalt analysis of claims to determine their patent-eligibility.

In the *Flook* case, Justice Stevens in his majority opinion brushes the “considered as a whole” argument aside rather cursorily, rather than asserting its inapplicability and basic wrongness. Indeed, he (unnecessarily) concedes its applicability without citing any authority. He then says that his analysis does consider the claim as a whole:

“Our approach to respondent’s application is, however, not at all inconsistent with the view that a patent claim must be considered as a whole. Respondent’s process is unpatentable under § 101 not because it contains a mathematical algorithm as one component, but because, once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.”

That is to say, once you analytically dissect out the algorithm the remainder of the claim considered as a whole contains nothing that qualifies for a patent. (It is all conventional and well known.) If this is satisfactory analysis, it is only on the principle that any stick is good enough for beating a bad dog. To be fair to Justice Stevens, however, he sees it as what the inventor purported to have invented. When it is conceded that the implementation is old and conventional, and that the only inventive contribution is using the algorithm in this context, he sees the case as one in which the inventor (constructively) does not purport to have invented anything. That is what he means when he says that Flook’s patent application, “considered as a whole, contains no patentable invention”. In so holding, he implicitly rejects the idea that applying an old or new algorithm in a new context, where everything present operates as it has conventionally done in the past and no unexpected new functionality emerges, can legitimately purport to be an act of invention.

The idea of considering the “whole” of a claim involving a principle to determine the claim’s patent-eligibility is almost entirely a “bad dog”. If all the elements of a claim have zero patent-eligibility value, their sum is also zero. $0 + 0 = 0$. Unless there is some identifiable advance in the co-operation of claim elements, specifically the co-operation of the algorithm with the other elements, nothing can be gained by insisting on a gestalt analysis. Copyright law is right to use analytic dissection to try to minimise the confusion that making a complex and difficult analysis begets, and patent law should emulate its sibling. There is a limit to how many difficult concepts one’s mind can juggle at one time, and it is a short list. Sensible problem-solving methodology for complex problems has long been to break the problem down into separate parts and then to try to solve each part, one at a time. The same principle applies here when the parts of the claimed subject-matter are all old, they operate in their usual way, and they co-operate with one another in a conventional, foreseeable manner. The only possible exception, and this is where “considered as a whole” is not a bad dog, would be if the natural principle co-operated with the other elements in a new, and preferably unexpected, way to bring about some improvement. If it somehow happened that would give a reason to take a more holistic approach. Otherwise, however, it would be unjustified and would invite judicial mistake and capriciousness. That other side of the coin in *Flook* features centrally in *Prometheus*’s analysis of Diehr 30 years later.

**The Diehr case**

In the *Diehr* case, the last member of the trilogy of late 20th-century patent-eligibility cases, the claim was held patent-eligible. Diehr devised an improved method for curing synthetic rubber articles in a mould. He used the known Arrhenius equation to determine when synthetic rubber had been heated long enough in a mould to cure it, the appropriate cure time being a function of the successive temperatures inside the mould, which were constantly monitored by thermocouples and fed to a general-purpose digital computer.

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60 35 USC §103.
61 35 USC §101.
62 See, e.g., *Keene Corp v United States* 508 U.S. 200, 208 (1993) (“This fact only underscores our duty to refrain from reading a phrase into the statute when Congress has left it out.”) ["Where Congress includes particular language in one section of a statute but omits it in another ... it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion"] (quoting Russello *v United States* 464 U.S. 16, 23 (1983)).
66 35 USC §101.
67 See, e.g., *Keene Corp v United States* 508 U.S. 200, 208 (1993) (“This fact only underscores our duty to refrain from reading a phrase into the statute when Congress has left it out.”) ["Where Congress includes particular language in one section of a statute but omits it in another ... it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion"] (quoting Russello *v United States* 464 U.S. 16, 23 (1983)).
68 See, e.g., *Keene Corp v United States* 508 U.S. 200, 208 (1993) (“This fact only underscores our duty to refrain from reading a phrase into the statute when Congress has left it out.”) ["Where Congress includes particular language in one section of a statute but omits it in another ... it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion"] (quoting Russello *v United States* 464 U.S. 16, 23 (1983)).
70 In his *Discourse on the Method of Righdy Conducting One’s Reason and of Seeking Truth in the Sciences* (French title: Discours de la méthode pour bien conduire sa raison, et chercher la vérité dans les sciences), Part II (1637), Descartes prescribes as his second precept “divide each of the difficulties under examination into as many parts as possible, and as might be necessary for its adequate solution”.
71 Stevens at times says a new or unconventional way and other times says unobvious. In *Prometheus* Breyer says unconventional and unobvious. Both of them rely on *Neilsen* to say that patent-eligibility cannot be drawn from the principle itself, for that is a zero in the patent-eligibility calculus.
The computer fed the temperature data into the Arrhenius equation and signalled when the appropriate cure time had been reached. Diehr’s process may be compared to a process for roasting a rib roast of beef, which you desire to cook medium rare. You turn on the oven, insert the probe of a meat thermometer into the meat, adjust the movable indicator to Beef Medium Rare 145°F, put the rib roast into the oven; and shut the oven door (see Figure 2). Then you watch the thermometer needle move around the dial. When the needle coincides with the indicator, you take the rib roast out of the oven.

In describing the Diehr opinion, three decades later, the Prometheus court says, with a straight face:

“These other steps apparently added to the formula something that in terms of patent law’s objectives had significance—they transformed the process into an inventive application of the formula.”

And that furnished the basis in Prometheus for eliminating conflict between Diehr and Flook, for harmonising them, and avoiding Diehr’s standing as an obstacle to the judgment in Prometheus.

In a blistering dissent, Justice Stevens accused the majority of overruling Flook without being willing to admit it. Stevens made no effort to concur (in the style of Breyer) and put a spin on Diehr to preserve the core of Flook. In Stevens’s view, the facts in Diehr are indistinguishable from those of Flook, and that is determinative:

“There is no suggestion that there is anything novel in the instrumentation of the mold, in actuating a timer when the press is closed, or in automatically opening the press when the computed time expires.”

In fact, he observes, the claimed process is even similar to a method of updating alarm limits:


69 *Diehr* 450 U.S. 175, 187 (1981). It is unknown whether other old and conventional alternative steps existed for moulding rubber articles, for the opinion is silent on that.

70 *Prometheus* 132 S. Ct. 1289, 1299 (2012).

71 The following comments in Diehr about analytic dissection are, or effectively are made, obiter dicta under Prometheus’s analysis of Diehr, because in Prometheus Diehr’s invention is patent-eligible whether considered as a whole or subjected to analytic dissection. The “other steps of the claimed process or their combination added to the [Arrhenius] formula something that ... transformed the process into an inventive application of the formula.” Prometheus, 132 S. Ct. 1289, 1299 (2012).

72 *Diehr* 450 U.S. 175, 188-189 (1981). As already indicated, the right answer is somewhere in between. If the formula is the only novel element its presence should be ignored in the analysis if and only if it co-operates with the other elements in a conventional and expectable manner.

73 *Diehr* 450 U.S. 175, 208 (1981). As pointed out in Prometheus, however, there is no suggestion to the contrary. See text following supra fn. 68-69.
Diehr marked the end of the court's interest in patent-eligibility for three decades,\textsuperscript{57} until the 2010 Bilski opinion. We turn now to the Prometheus opinion. The claim under analysis in Prometheus

Before considering the main issues involved in Prometheus, a preliminary point deserves attention. The representative claim that the Supreme Court considered\textsuperscript{58} is drafted atrociously.\textsuperscript{7} There is a reason for that, but not a good one.

Although styled “a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder”, the claimed process does no treating except in the first (“administering”) step, which is old, and it does no optimising at all. The claimed process only directs a user of the process to administer a drug that metabolises to 6-thioguanine and then determine a blood level of 6-thioguanine; it directs no further acts. The remainder of the claim—a pair of wherein clauses—is simply a didactic statement, which technically is neither an act nor a true claim limitation. The optimising method as claimed is incomplete.

This creates one of the problems with the claim. It allows anticipation by the prior art. Such mere didactic observations as those of Prometheus’s wherein clauses do not limit and thus effectively distinguish the claim’s only recited acts from the prior art. And surely some doctors in the past have administered a thiopurine and ascertained the resulting blood level of 6-thioguanine,\textsuperscript{79} thereby practising and thus anticipating the only acts specified in what this patent claims. The wherein clauses sought to distinguish the claim over the prior art, but they were ineffective expedients. That raises the question of why did Prometheus not simply recite the acts of increasing or decreasing drug dosage according to the assay results. That is what a claim draftsman considering “a method of optimizing therapeutic efficacy for treatment …” \textsuperscript{80} would normally do. That would distinguish the claim from the prior art, assuming that doctors were not previously making a point of staying above 230 and below 400 pmol of metabolite when dosing their patients. But there is a difficulty with claiming the complete method. Prometheus had a business reason to draft its claim without the acts of increasing or decreasing drug dosage according to the assay results. Prometheus does not treat patients as a doctor would. It is a laboratory that sells diagnostic services to hospitals or doctors, and so are its competitors. Prometheus wants to be able to sue laboratory competitors that offer the same assay. But like Prometheus, such laboratories do not perform the steps of increasing or decreasing drug dosage for patients to whom they administer drugs.

If the process claim were complete, competitive laboratories would not directly infringe the patent by using the assay in competition against Prometheus, because they do not perform all of the steps. A process claim is directly infringed only if the accused infringer performs each step of the claim; omission of any step avoids direct infringement.\textsuperscript{80} Prometheus could therefore successfully sue competitive laboratories, if at all, only for inducing infringement or contributory infringement—the elements of proof for which are notoriously troublesome.\textsuperscript{80} To be in a position to sue competitors for direct infringement and sidestep the difficulties of proving induced or contributory infringement, Prometheus needed to avoid directly

\textsuperscript{54} Diehr 450 U.S. 135, 208 (1981).
\textsuperscript{55} There was one exception, however, although of little significance to patent-eligibility doctrine. The court approved the eligibility of newly developed sexually reproduced plants for utility patent protection in \textit{J.E.M. Ag Supply v Pioneer Hi-Bred Int’l} 534 U.S. 124 (2001). In addition, there was an abortive effort in \textit{LabCorp of Am. v Metabolite, Inc} 548 U.S. 124 (2006), to review the judgment in a case much like Prometheus. After granting certiorari, the court dismissed the writ as improvidently granted. Justice Breyer, with whom Justices Stevens and Souter joined, dissented from the dismissal as unwarranted, stating that what was claimed was a natural principle, for reasons similar to those given in the Prometheus opinion. \textit{LabCorp} at [138].
\textsuperscript{56} See text following fn.11 above.
\textsuperscript{57} There has been a great deal of protest among members of the US patent bar that the claim that the Supreme Court addressed in Prometheus is bad and therefore should not be the basis of an important precedent. I think that this grumbling reflects resentment and some sort of wishful thinking by the bar that the underlying ruling of a unanimous Supreme Court could and should be made to go away because the patent bar do not like it. The problem with Prometheus’s claim is not one of craftsmanship. It is far more fundamental, and proper drafting would not cure the claim or change the result, as becomes clear when the claim is revised properly.
\textsuperscript{58} The opinion says as much: Prometheus 132 S. Ct. at [1289], [1295] (2012).
\textsuperscript{59} Actually this claimed invention, as claimed, is not so much a method of optimising treatment as it is a method of determining how to optimise treatment.
\textsuperscript{60} Cainton Bio-Medical, Inc v Integrated Liner Technologies, Inc 216 F. 3d 1367, 1370 (Fed. Cir. 2000) (“Infringement of process inventions is subject to the ‘all-elements rule’ whereby each of the claimed steps of a patented process must be performed in an infringing process, literally or by an equivalent of that step, with due attention to the role of each step in the context of the patent invention”); EMI Group North America, Inc v Intel Corp 157 F. 3d 887, 896 (Fed. Cir. 1998) (“For infringement of a process invention, all of the claimed steps of the process must be performed, either as claimed or by an equivalent step”).
reciting the dosage steps in its claim. That is what it tried to do: draft a claim that its competitors would directly infringe if they used the assay, but it failed.

In addition, Prometheus had a “single actor” problem. There is no direct, indirect, or contributory infringement if the steps of a method claim are not all performed by a single actor (or its contractual obligor or agent operating under its control). If doctors perform the administering step and laboratories perform the assay, there is no single actor.

In sum, first, Prometheus claimed an anticipated process. Secondly, it probably also wrote a claim that doctors perform the administering step and laboratories perform the assay, there is no single actor.

To accomplish Prometheus’s purpose properly, it could have written the claim something along these lines (underlined italic = added words; strikethrough = deleted words; ordinary font = unchanged words):

“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) (a) determining the blood level of 6-thioguanine in a subject to whom a drug metabolizing to 6-thioguanine has been administered for treatment of said subject having said immune-mediated gastrointestinal disorder;

wherein if the level of 6-thioguanine is less than about 230 pmol per 8 x 10^8 red blood cells, providing a first physical output signal, wherein said first physical output signal indicates a need to increase the amount of said drug subsequently administered to said subject; and

(c) wherein if the level of 6-thioguanine is greater than about 400 pmol per 8 x 10^8 red blood cells, providing a second physical output signal, wherein said second physical output signal indicates a need to decrease the amount of said drug subsequently administered to said subject; and

wherein said first physical signal and said second physical signal are each selected from the group consisting of written statements, audible sounds, visually perceptible signals, and electronic control signals.”

This claim distinguishes what is claimed from the prior art; laboratories, but not doctors, directly infringe it; and there is a single actor (the laboratory). That said, we may ignore the issue of claim defects, if any, and assume that there is no objection on formal grounds to addressing the patent-eligibility of the claimed invention of Prometheus’s scientists. That gets rid of an irrelevant possible issue. The question then becomes purely one of whether what is claimed is still patent-ineligible despite any technical fix-up of the claim, because it claims a natural principle. The answer remains the same.

Harmonising the case law

As suggested earlier, the Prometheus opinion contains a remarkable harmonisation of case law that one might have thought impossible to harmonise. The main problem is harmonising Diehr with Flook. One reading of Diehr would have it rejecting analytic dissection and demanding “as a whole” analysis of a claim’s patent-ineligible parts along with any patent-eligible parts; upholding the patenting of an old process performed with old machinery, aided by a known computer conventionally making calculations with an old equation, a process with no new elements (or steps) and no new form of co-operation among the elements; and overruling Flook sub silentio while pretending not to do so. In his Diehr dissent that was how now-retired Justice Stevens had read the Diehr majority opinion. But that is not how Justice Breyer chose to read that opinion.

Beginning with the facts, he capitalises on the Diehr opinion’s failure to confront Justice’s Stevens’s assertions as to the facts. To Breyer, nothing in the Diehr opinion can be read to suggest that the steps of the claimed process or their combination “were in context obvious, already in use, or purely conventional”, as in Flook. He then opines that the majority must have seen something unobvious or unconventional about them:

82 Prometheus sought to accomplish mutually exclusive objectives. It wanted the references to 6-thioguanine levels to distinguish the claim from the prior art but at the same time it wanted the references not to be claim limitations that would permit competitive laboratories to escape direct infringement. That required a more oblique approach than Prometheus used. Ordinarily, what is a limitation for validity purposes is also a limitation for infringement purposes. See, e.g., Angen Inc v Hoechst Marion Roussel, Inc 324 F. 3d 1313, 1330 (Fed. Cir. 2003) (“It is inescapable that claims are construed the same way for both validity and infringement”); C.R. Bard, Inc v M3 Systems, Inc 157 F. 3d 1340, 1363 (Fed. Cir. 1998) (“Claims must be interpreted the same way for determining infringement as was done to sustain their validity”). Therefore, something besides “determining” must be put into the claim as a limitation, it must not be part of the prior art, and it must be something the competitors do.

83 McKesson Technologies Inc v Epic Systems Corp 2011 U.S. App. LEXIS 7531 (Fed. Cir. April 12, 2011) (“This court has time and again rejected liability where one party performed most of the patented method and left it to another party to complete the method in the absence of any contractual obligation or agency relationship that would vicariously attribute the acts of the one party to the other”); BMC Resources, Inc v Paymentech LP 498 F. 3d 1373, 1379 (Fed. Cir. 2007) (“Indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement”). The McKesson case is pending en banc review.

84 See A王朝 Technologies, Inc v Limelight Networks, Inc 629 F. 3d 1311, 1320 (Fed. Cir. 2010) (“There can only be joint infringement when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps”). This case is pending en banc review.

85 The wherein clauses at the end of steps (b) and (c) and in the last paragraph are not necessary but they make the claim more informative to a judge or jury. Also, one might want to provide a third signal for blood levels between 230 and 400 pmol, indicating no need to modify dosage.

86 Prometheus 132 S. Ct. 1289, 1299 (2012).
"These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.\textsuperscript{87}

For these reasons, the unanimous \textit{Prometheus} court concluded, \textit{Diehr} does not conflict with \textit{Flook} and does not impair its doctrine against patenting obvious or conventional implementations of patent-ineligible principles. \textit{Diehr redux} is left limited to its supposed facts and \textit{Flook} regains all its authority. Neilson is rehabilitated at the same time. It and \textit{Flook} support the propositions that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable"\textsuperscript{88} and conversely that including unconventional, unobvious, inventive elements to the implementation of a natural principle is a sine qua non of patent-eligibility in such cases.

The opinion does not directly confront \textit{Diehr}'s depreciation of analytic dissection or its enthusiasm for considering the claim as a whole.\textsuperscript{89} Indeed, the word "dissect" does not occur in the \textit{Prometheus} opinion, although its methodology is analytic dissection throughout. The approach in \textit{Prometheus} to \textit{Diehr}'s holding the process patent-eligible based on an analysis of the claim considered as a whole is to co-opt that part of the \textit{Diehr} opinion and transform it into conventional wisdom by viewing the facts of the case with imagination or perhaps a spin. As indicated earlier, \textit{Prometheus} sees \textit{Diehr} as a case in which the "other steps apparently added to the formula something that in terms of patent law's objectives had significance", and that was that they co-operated in a novel and inventive manner with the formula, so that "they transformed the process into an inventive application of the formula."\textsuperscript{90} Novel and superior co-operation or co-action among a combination of elements is a classic basis to set the combination apart from the prior art, even if the elements are individually old.\textsuperscript{91} This treatment of \textit{Diehr} thus sets the stage for \textit{Diehr redux} to provide the other side of the coin from \textit{Flook} and \textit{Prometheus}—unconventional implementation of the underlying principle in \textit{Diehr redux} but conventional and therefore patent-ineligible implementation in \textit{Flook} and \textit{Prometheus}.

Metaphorically, this verbal jujitsu seizes and grapples \textit{Diehr}, applies some leverage, and throws it into a corner. This surely is head and shoulders above the usual run of work at the Supreme Court.

\textbf{Applying these rules to the case at bar}

The \textit{Prometheus} case presented a prime example of over-claiming in the manner of \textit{Morse}. The claim to all assays that exploit the principle that these drugs should be dispensed at a dosage level that results in a level of metabolite between about 230 and about 400 pmol, no matter what form of assay or therapeutic regime is used, risks inhibiting future innovation in the field and discourages others from attempting it. The \textit{Prometheus} patent "forecloses more future invention than the underlying discovery could reasonably justify."\textsuperscript{92}

The Federal Circuit had upheld the claim as patent-eligible because it thought it satisfied one branch of the machine-or-transformation test. The lower court thought that the claimed process caused a transformation—"transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels."\textsuperscript{93} Putting aside the perhaps dubious merits of the lower court's characterisations,\textsuperscript{94} there are more important reasons why this argument does not support patent-eligibility. The court responded to the transformation claim: "[W]e have neither said nor implied that the [machine-or-transformation] test trumps the 'law of nature' exclusion. That being so, the test fails here." That is so, but satisfying the machine-or-transformation test is not enough to guarantee patent-eligibility, even when a natural principle is not involved.

\textsuperscript{87} \textit{Prometheus}, 132 S. Ct. 1289, 1299 (2012). This requires some willing suspension of disbelief, but it is a legitimate reading of the test of \textit{Diehr}: In any case, this article accepts throughout the analytic assumptions or principle that a precedent "says" (for purposes of US law) what the present majority of the US Supreme Court claims that it says: later holdings can change the meaning of earlier holdings. This is the jurisprudential equivalent of "Parliament can do no wrong". See generally \textit{City of London v Wool} (1701) 88 E. R. 1592 at 1602; 12 Mod. 669 at [688] (KB) (Holt C.J.) ("Parliament can do no wrong, though it may do several things that look pretty odd").

\textsuperscript{88} \textit{Prometheus}, 132 S. Ct. 1289, 1300 (2012).

\textsuperscript{89} See \textit{Salazar v. Ag Pro, Inc.} 425 U.S. 235, 282 (1976) (combination implementing natural principle "adds nothing to the sum of useful knowledge where there is no change in the respective functions of the elements of the combination" so that combination is obviously patent-ineligible under §103); Anderson's \textit{Black Rock, Inc v Pavement Salvage Co} 396 US 57, 60 (1969) ("The combination of putting the burner together with the other elements in one machine ... did not produce a new or different function within the test of validity of combination patents") (internal quotation and citation omitted).

\textsuperscript{90} \textit{Prometheus}, 132 S. Ct. 1289, 1301 (2012). Apparently, it would have made no difference in patent-eligibility if the claim had contained a step or steps for conventionally dosing (e.g. pill or intravenous) the patient in accordance with the assay result. Nothing conferring patent-eligibility would be added to the natural principle by such conventional steps.

\textsuperscript{91} \textit{Prometheus}, 132 S. Ct. 1289, 1302 (2012).

\textsuperscript{92} "Transforming" a patient's blood by analysing in a laboratory a sample of it extracted from the patient's body is not the kind of transformation the cases recognise. The transformation must change what the process operates on to a different end product, a change from one substance to another—for example, vulcanising India rubber, smelting ores, manufacturing fatty acids and glycerine from fatty bodies, artificially incubating eggs to transform them into chickens. See \textit{Benson} 406 U.S. 63, 70–71 (1972). Transforming a patient's body by curing an autoimmune disease with thiopurine was a legitimate transformation but someone else's invention or discovery, so that \textit{Prometheus} could not patent it.

\textsuperscript{93} \textsuperscript{(1701)} (£163)

For example, if use of an invention offends public policy, even a machine or transformation cannot be patented. Moreover, if an improvement is clearly not within the “useful Arts” to which the US Constitution limits congressional patent power, the improvement cannot be patented.97

It warrants emphasis that the machine-or-transformation test is not a policy in its own right. It is merely instrumental, a means for judging the pre-emptiveness of a principle-implementing claim. The machine-or-transformation test is not a positive test that if satisfied confers patent-eligibility on a claim; it is a negative test that if not satisfied typically leads to patent-ineligibility, so that satisfying the machine-or-transformation test is not a sufficient condition for patent-eligibility.

More important, as Prometheus tells us:

“[A] process that focuses upon the use of a natural law [must] also contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”98

That statement hints at a positive test of patent-eligibility but does not explicitly disclose it by telling us in so many words how to recognise when a claim “amounts to significantly more than a patent upon the natural law itself”.

But Prometheus’s harmonisation of the case law gives us ample and powerful clues: we can examine its view through rose-tinted lenses of Neilson and Diehr and look at the opposite side of the patent-ineligibility holdings in Benson and Flook. By doing that we discern how to recognise when a claim goes beyond a mere statement of a natural principle. What Prometheus instructs is this:

- The implementation of the principle must add to the principle more than just the conventional expedients that scientists or artisans in the relevant field know and use, or the implementation should at least purport to do so (the lessons of Prometheus and Flook).
- A novel apparatus helps (Neilson reduc).
- Novel co-operation or co-action is very helpful (Diehr reduc).
- The claims should not be open-ended and exceed what the inventor has taught the public to do to exploit the principle (Morse).

That is how Prometheus teaches us to recognise when a claim “amounts to significantly more than a patent upon the natural law itself”.

The war between section 101 and sections 102–103

Finally, it was argued that “virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101’s demands” and all remaining screening functions should be performed by §§ 102 (novelty), 103 (obviousness), and 112 (enableness and definition description).99 The court emphatically rejected this view as corrosive of the patent system.

This approach, the court protested, would make the accumulated law of § 101 and its predecessor provisions dating back to the first US patent act99 a “dead letter”.100 The case law dating back to the 19th century against patenting ideas, principles of nature and the like is not codified in §§ 102, 103, or 112, and therefore would be abrogated by this proposal. Only § 101 addresses such doctrines, by limiting the grant of a patent to a person who “invents or discovers” a new “process, machine,
manufacture, or composition of matter”, within the meaning that the case law gives those terms. Although to some extent the § 101 inquiry may overlap with the others, they need not always do so and:

“[T]o shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.”

The nutshell

Prometheus resolves several related issues. First, it re-emphasises the quasi-jurisdictional importance of patent-eligibility as a threshold inquiry that must be resolved in patent cases involving claims to implementations of: natural laws; phenomena of nature; equations of physics, chemistry, or mathematics; algorithms; and abstract ideas (collectively “principles”). Second, unwarranted pre-emption of the innovative efforts of other potential inventors remains an important policy consideration in judging patent-eligibility. Third, implementations of principles in a purely conventional or obvious manner are likely to be held patent-ineligible. In the same vein, conventional implementations of principles are now more likely to be judged pre-emptive under §101 than relegated to an obviousness analysis under §103.

Fourthly, the analytic dissection methodology appears to be in a stronger position than “considered as a whole” in determining patent-eligibility.

But what’s a natural principle?

One issue that will doubtless generate more litigation is the scope and meaning of the terms natural principle and phenomenon of nature. One case testing that will probably come before the court in the next or following term—the Myriad case, allowing some gene patents.

The outer limits

More generally, the outer limits of the concept of principle are not well defined. Clearly, principles of physics and chemistry, such as the inverse square law for radiation and the law of mass action, qualify as natural principles. So, too, do empirical laws such as the effective dosage amount and toxic dosage amount of a given drug, which Prometheus involved. But what of more poorly understood inventions or principles? Very old inventions can illustrate this issue. For example, consider the canary in the coal mine or the fact that you can get clothes clean by submerging them on a rock in a stream and beating them with a stick. Are these natural principles? The objection may be raised that you cannot properly tell that something is a natural principle when you do not know what the principle is. Furthermore, is everything you cannot understand to be held a natural principle? That greatly expands the doctrine and collides with the legal rule that inventors are entitled to patents even if they do not know how or why their invention works. Certainly, inventors who do not understand the underlying principle cannot very well submit claims that pre-empt the principle, so that the law need not penalise them in order to raise a fence against that risk.

Those (such as the pharmaceutical industry) who fear or otherwise disapprove of Prometheus’s doctrine against patenting natural principles assert that the aftermath of Prometheus might be that the doctrine will expand to obliterate or at least threaten all patents, because ordinarily some principle is implemented to some extent in any patented invention. But one limit to such expansion is that the doctrine does not purport to obliterate invented implementations of natural principles, as Morse’s repeater apparatus was and as Prometheus says that Diehr’s device was. Another limit is that inventors are not obliged to claim so pre-emptively that, as with Morse’s claim 8, they exceed the bounds of what they have taught the

103 For example, “process” has a common sense everyday meaning that would embrace the processes that Benson, Flook and Bilski claimed. But that is not the statutory meaning of the term, as the court held in Flook 437 U.S. 584, 593 (1978) (“The rule that the discovery of a law of nature cannot be patented rests not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect”). The Supreme Court “forecloses a purely literal reading of section 101”: Flook at [588]-[589].

104 Prometheus, 132 S. Ct. 1289, 1304 (2012).

105 One consequence of that is that such secondary considerations as commercial success are likely to receive less weight, if any at all, under §101 than under §103.

106 In Association for Molecular Pathology v US Patent and Trademark Office 653 F. 3d 1329 (Fed. Cir. 2011) (known as the Myriad case), the Federal Circuit held isolated breast cancer related natural DNA nucleotide sequences patent-eligible and edited such DNA patent-eligible. The latter are fragments of natural DNA with some gene sequences cut out because they are not functional in a manner designed. The case was co-pending with Prometheus, and after that case was decided the Supreme Court vacated Myriad and remanded it to the Federal Circuit for reconsideration in the light of Prometheus. Like ideas, algorithms and natural principles, which are “the basic tools of scientific and technological work” (see Benson 409 U.S. 65, 67 (1972); Flook 437 U.S. 584, 589 (1978); Prometheus 132 S. Ct. 1289, 1302 (2012)), gene sequences are the basic tools of genetic technology work. The same legal principles may therefore apply: it may make a difference, however, whether the editing is conventional or trivial; it may also matter how pre-emptive the claim is—for example, would it pre-empt the breast cancer research of all other workers in the field? The Federal Circuit has set the remanded case for argument in July 2012. However the Federal Circuit decides Myriad, the large interests at stake are sure to bring the case before the Supreme Court.

107 See Diamond Rubber Co v Consolidated Rubber Tire Co 220 U.S. 428, 435–436 (1911) (“It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention”); Newmac v Quigg, 877 F. 2d 1575, 1581 (Fed. Cir. 1989) (“It is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works”). The inventor merely must teach the public what they must do to use the invention. Diamond at [436].
Recently, another limit, which most of the remainder of this article considers, is that provided by custom and history. How far does Prometheus take us? I suppose the answer is "until we say 'Toto, I've a feeling we're not in Kansas anymore'". And when do we say that in this context? Perhaps a few hypotheticals will illustrate Pharma's concerns or possibly the extent of its representatives' overheated imaginations.

Consider a method of treating such-and-such a disease comprising dosing a subject with such-and-such a dosage amount of such-and-such a known drug chemical conventionally formulated into a tablet. What distinctions are proper for patenting processes for using such drugs therapeutically, for patenting conventional pharmaceutical compositions containing such drug chemicals, and for patenting the drug chemicals themselves? Each of these can implement a natural principle in much the same way. Are differences in patent-eligibility appropriate? The Prometheus decision has caused representatives of patent holders in the pharmaceutical field to express concern (even alarm) over the possible implications of Prometheus.

To continue more specifically along this line of inquiry, suppose I discover that thiopurines (a known chemical) in such-and-such a dosage can cure Crohn's disease, and I want to patent this therapeutic method. That fact or principle would seem to be a law of nature, an eternal truth, what Prometheus calls a consequence of how the human body operates. Prometheus and Funk suggest that my hypothetical claim to a patent monopoly over "a method of treating Crohn's disease, comprising administering such-and-such a dose of thiopurine to a person with Crohn's disease" could fail as patent-ineligible. Is that discovery different in principle from discovering that certain strains of Rhizobium bacteria are not mutually antagonistic or that a dose of thiopurine generating more than 400 pmol of 6-thioguanine risks a toxic reaction? New drug uses of old chemicals may be in for a rough trip, if deemed natural principles. But the patent statute gives them at least some recognition. Section 100(b) states that the term "process" includes a new use of an old product. Does that trump the doctrine against patenting natural principles? Prometheus held that the machine-or-transformation test did not "trump the 'law of nature' exclusion" from patent-eligibility. But the machine-or-transformation test is a principle of case law while now we speak of a statute. Section 100(b) arguably is a congressional declaration that new uses of old chemicals are patent-eligible processes if they are inventive. Does § 100(b) go so far as to say that the discovery of a new use is automatically an invention? One might argue that so holding conflicts with § 101's requirement that the subject-matter be "invented" to be patented, which evokes the Constitution's requirement that patents are only for inventors' inventions. Can a natural principle, if that is what a new use of an old chemical is, be an invention of an inventor? Must not the implementation of such a discovery itself be inventive?

That raises the question of the source of the "law of nature" exclusion from patent-eligibility. If it is purely statutory, § 100(b) arguably trumps it (the specific statutory provision governing over the general). But if it derives from the constitutional limitation on patents, and if that terminology excludes laws of nature and non-inventive implementations of them, as it likely does, the statute cannot trump the exclusion. Statutes cannot trump the Constitution. The Constitution is the supreme law of the land. The 19th-century cases in England and the United States that state that no one may have a patent on an idea or natural principle say nothing of the legal basis for that rule, nor do such later cases as Funk, &;
Benson, Bilski or Prometheus, while a US decision contemporaneous with Morse simply asserts that a principle is a “fundamental truth” that “cannot be patented” because “no one can claim ... an exclusive right” in it.114 No reported case of which I am aware gives any legal explanation of why fundamental truths cannot be patented, although the disastrous impact on public policy of granting such patents seems indisputable,115 as Prometheus recognises.116 One could say that such patents are “against the common law”,117 but that argument runs into the rule that the legislature can change the common law by statute unless (in the United States) the Constitution prevents that particular change.118 This puzzle defies a ready answer, but turning § 100(b) into mostly a dead letter, and invalidating many of those patents based on it (and dashing their owners’ expectations), would daunt many judges.

Now suppose that I manipulate the thiopurine molecule—add a methyl there, subtract a nitryl there—and devise a modified, hitherto unknown thiopurine that works better than the thiopurine in use until now. Will my synthesis of the new compound distinguish my product from the preceding examples? Will it lead to patents on the chemical, the process of its synthesis, its embodiment in a conventional pharmaceutical composition, or my therapeutic method? Is there a difference in the natural principle status of new and old chemicals? Are the properties of new chemicals eternal truths? Unpatentable forms?

Consider $E=mc^2$. There was no $E=mc^2$ in any book or anywhere in the real, physical world until Einstein first derived the equation and wrote it out. Was it nonetheless an eternal verity pre-existing in the world of archetypes? The cases act as if the answer is yes119; certainly that is what Prometheus implies. Is my hypothetical molecular manipulation of thiopurine any different in principle? Was not it too lurking at the side of Plato’s cave waiting for someone to shine a torch behind it, cast its shadow on the wall, and thus instantiate it? On that basis, should new drug chemicals and their therapeutic properties be considered natural, albeit hitherto unrecognised, principles?

This seems hard to accept, given the long-established practice of patenting new chemicals. It is unlikely that the Supreme Court would go this far; surely, we are not in Kansas anymore and have collided with other principles that limit the expansion of the doctrine of the Prometheus case. Probably, for the last several hypothetical cases the limit of Prometheus will be set by existing expectations on which substantial commercial reliance “justifiably” rests.

### Biopharmaceuticals

One area of pharmaceutical innovation may raise closer questions. So-called biopharmaceuticals are large-molecule drugs produced by biotechnology.120 Biopharmaceuticals are often produced from microbial or mammalian cells, and their manufacture thus mimics natural processes that produce the same product or a naturally occurring product very similar to it. Biopharmaceuticals can also be produced by turning animals into drug-manufacturing “machines” by genetically modifying them.121 The products of such technology are often artificially manufactured natural products, which have long been held unpatentable.122

The doctrine of the Prometheus case may well apply to biopharmaceuticals, as such, although the process for manufacturing them, at least if dissimilar to a natural process, would seem to be patent-eligible. To the extent that the process in question closely mimics the corresponding natural process, the more likely it is that a Prometheus problem will exist. In a case where a host animal is infected with human genes for manufacturing a drug, it may be said that such and such genes manufacture this product in the same way they always did in a mammal; they produce the same product, and the

115 Perhaps this is misguided, but I would have felt more comfortable if some one of the jurists writing these opinions had found a suitable quotation in Coke on Littleton on things in which can and cannot be property or had made an analysis of how the words in the patent clause of the Constitution required this conclusion. For example, if one believes in the eternal verity/Tunas a dead letter, and invalidating many of those patents based on it (and dashing their owners’ expectations), would daunt many judges.
116 Prometheus 132 S. Ct. 1289, 1301 (2012) (because natural laws are “the basic tools of scientific and technological work”, patents on natural laws “foreclose more future invention than the underlying discovery could reasonably justify”).
118 Brown v Barry 5 U.S. (3 Dall.) 365, 367 (1797) (holding that statute, “being, in derogation of the common law, is to be taken strictly”); but nonetheless acknowledging power of legislature to change the common law; see also Roscoe Pound, “Common Law and Legislation” (1908) 21 Harv. L. Rev. 383, 396 (“Courts could not entertain a suggestion that legislation contrary to the doctrines of the common law is invalid”).
119 Sec., e.g., Flook 437 U.S. 584, 593 n.15 (1978) (“The underlying notion is that a scientific principle, such as expressed in respondent’s algorithm, reveals a relationship that has always existed”). The court then refers to Newton’s law of gravitational attraction $F=\frac{Gm_1m_2}{r^2}$, and endorses the proposition that “this relationship always existed—even before Newton announced his celebrated law. Such mere recognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment”.
120 The first such substance that FDA approved for therapeutic use was biosynthetic human insulin made by recombinant DNA technology.
121 An antiarrhythmic drug duplicating the antiarrhythmic action of human body products is made from milk of goats genetically modified with human genes. FDA has approved the marketing of the drug (brand-name Acton) (The European Medicines Agency initially rejected its use in the EU but subsequently approved it.)
122 In American Wood-Paper Co v Fibre Disintegrating Co 90 U.S. 566, 596 (1874), the court held a patent on artificially manufactured paper-pulp invalid because “whatever may be said of their process for obtaining it, the product was in no sense new”. Similarly, in Cochran v Badische Anilin & Soda Fabrik 111 U.S. 293, 311 (1884), the court held that a claim to artificial alizarin (a vegetable dye stuff long known) was invalid—“[T]he product itself could not be patented, even though it was a product made artificially for the first time.”
genetic modification technology used is conventional, so that the steps of the process "add nothing to the laws of nature that is not already present". 123

Such a holding, of course, would incense the biopharmaceutical industry. They would point to their investment-backed expectations and demand a change in the patent law. Whether the court would be willing to poke this stick into a hornets’ nest is uncertain. Some stakeholders have already called for congressional action to overturn *Prometheus*. 124 It seems doubtful to me that such congressional action is likely, but addressing this question in depth is beyond the scope of this article. For the time being, at least, *Prometheus* will remain fully in effect and therefore it promises an interesting further aftermath. But how far the court will apply its principle to neighbouring fact patterns is quite unclear.

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123 *See Prometheus* 132 S. Ct. 1289, 1298 (2012). Similar considerations might apply to the use of conventional genetic engineering technology to transfer traits, such as herbicidal tolerance or production of natural insecticides (e.g. nicotine), into the germ plasm and seeds of crop plants. It may be argued that the transferred genetic traits then function in the plants grown from the seeds as they previously did in nature, and that no inventive concept has been added to the natural principle.

124 There are stakeholders on both sides, however; see *Prometheus* 132 S. Ct. 1289, 1304–1305, which is a substantial obstacle to congressional action.