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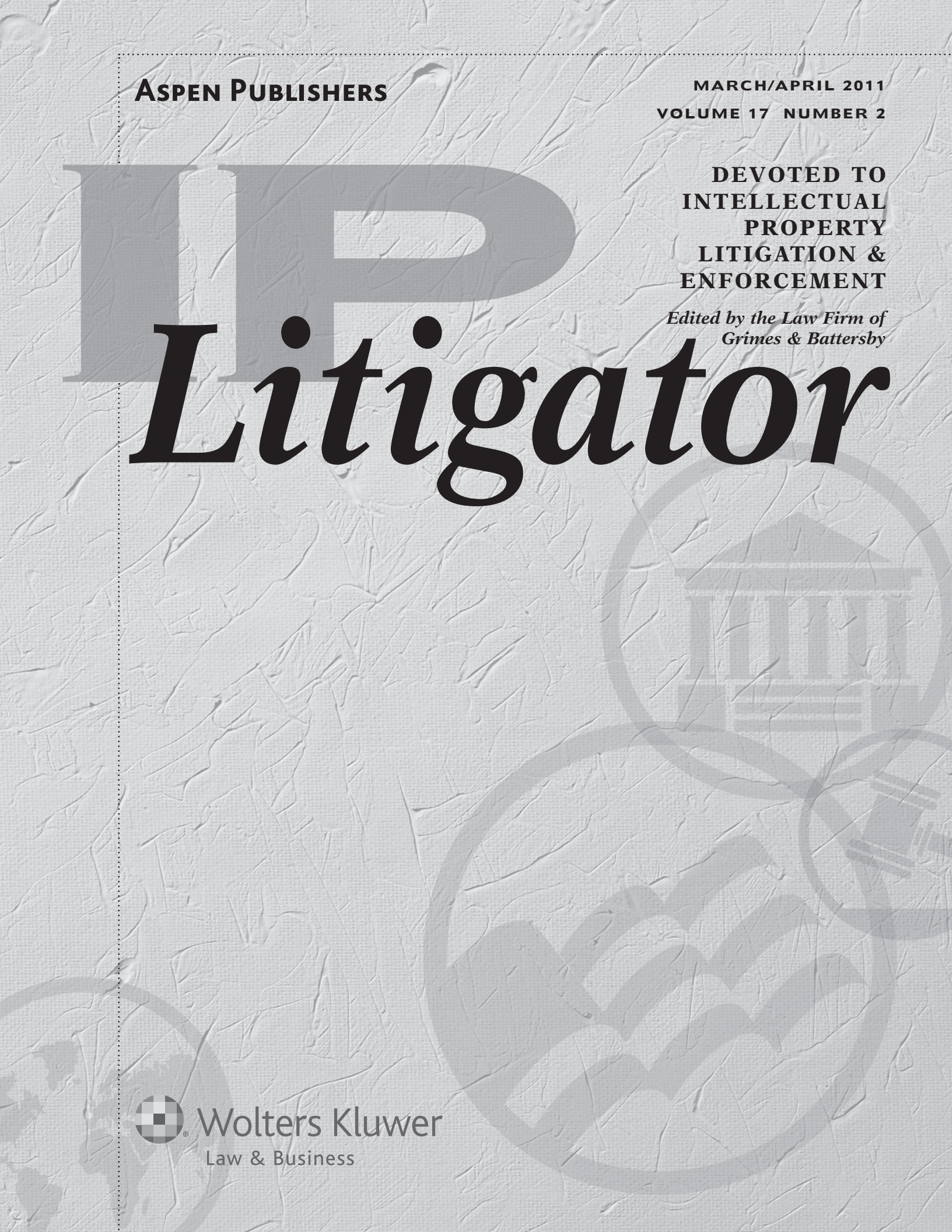

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How to Patent Business, Software, and Medical Diagnostic Methods in the Aftermath of the Bilski *Decision—Part 3, Diagnostic Method Patents*

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This is Part 3 of a three-part article and it examines what the Court's opinion means to the patenting of diagnostic methods. Part 1[1] explored what the Supreme Court's decision in *In re Bilski*[2] says on the law of 35 U.S.C. §101 and the standard for defining patentable subject matter. The tension between Sections 101 and 102/103 is explored along with analysis of how the "new and useful" standard of Section 101 differentiates from Sections 102/103 anticipation/obviousness. Part 2[3] delves deeper into what the Court's opinion means to the patenting of business and software methods and provides several practice pointers for use in drafting claims narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself.

Understand What Structure or Process Makes a Post-Solution Activity Not Insignificant

Will the thinking of the Court in *Bilski* be strictly limited to "process" patents or will it have spillover effects upon the patentability of the other categories of machine, manufacture, or composition of matter? "To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection."[4]

In the aftermath of *Bilski*, now more than ever, a practitioner needs to understand what structure or process makes a post-solution activity not insignificant. For diagnostic method patents involving chemical action, claim recitations central to the invention should recite the determining of chemical levels by other than visual inspection and not rely on naturally occurring samples for patentability; rather reciting transformation of biological or chemical samples. For diagnostic methods employing software, claim recitations central to the invention should comply with Supreme Court guidelines on patenting of software.

The law in this area is very unsettled with the Supreme Court providing little guidance other than explaining through *Benson*, *Flook*, *Diehr*, and now *Bilski* that a process claim must be tailored narrowly enough to encompass only a particular application of a fundamental principle, law of nature or physical phenomena rather than to pre-empt the principle, law of nature, or a physical phenomena itself.[5] Still, the precedent provided by the lower courts *post*-Federal Circuit machine-or-transformation test—a test not overruled but stripped of its exclusivity by the Supreme Court— as well as Federal Circuit precedent since the *Bilski* decision provides some insight into how the jurisprudence in this area might evolve and for that limited purpose is instructive.

The Supreme Court Precedent with Respect to Chemical and Other Process Claims May Provide Further Clues about the Patentability of a Diagnostic Method

Under the trilogy of *Benson-Flook-Diehr*, a process claim cannot be patented unless it is tailored narrowly enough to encompass only a particular application of a fundamental principle, law of nature, or physical phenomenon, rather than to pre-empt the principle, law of nature, or physical phenomenon itself. The Section 101 challenge post-*Bilski* has now become determining when a claim has preempted a fundamental principle, a law of nature, or a physical phenomena.

In some instances the preemption is readily discernable, such as it was in *Bilski*. The commodity contracts in *Bilski* amounted to a fundamental principle (an abstract idea) and their manipulation amounted to a preemption of that fundamental principle.[6] In accordance with the trilogy of cases, that preemption made the *Bilksi* claim ineligible subject matter. Similarly, any diagnostic method patents that amount to a manipulation of a fundamental principle also fail. But when does a diagnostic patent amount to preemption of a fundamental principle, a law of nature or a physical phenomena? A number of Supreme Court cases provide further guidance.

Further Clues about the Patentability of Diagnostic Methods Involving Software

Part 2 of this article, appearing in the January 2011 issue of *IP Litigator*, explored the effects of the Supreme Court's *Bilski* decision on software patents. From that discussion one thing is fairly clear. From the *Benson-Flook-Diehr* spectrum of software can be gleaned the likely threshold for software patentability; *to wit, the existence of a link of the software to a physical and tangible object.* The software in *Diehr* was held patentable because it connected (more specifically, the signals or data[7] generated by the software connected) to the physical and tangible objects of a "mold" and a "press" through the steps of "loading of the mold" and "opening of the press."[8] Patentability in *Flook* failed since the claims were without any such link. As discussed in Part 2 of the series, the "reaching out and touching" by the signals or data generated by the software of physical or tangible objects could occur *physically* as in *Diehr* or *virtually,* that is to say, by signals or data generated by the software instructions actually *representing* physical or tangible objects.[9] Apposite is the Federal Circuit decision on the appeal of *Research Corp. Techs. v. Microsoft Corp.*,[10] where an arguably virtual link was upheld under arguably a newly articulated "functional and palpable applications" test.[11]

For a diagnostic method having one or more steps central to the claim that involves software, the clue to the subject matter patentability of that method may lie in whether those steps exceed the threshold for software patentability. That may occur when those steps link the software to a physical or tangible object. This link can be a *physical link* wherein the signals or data generated by the software reach out and touch a physical or tangible object. One example of this might be where the software steps central to the diagnostic claim generates signals or data that "loads a container with a specimen" and/or "opens that container" at the end of the method *a la Diehr*. The link also can be a *virtual link* wherein the signals or data generated by the software reach out and touch a physical or tangible object *virtually,* by signals or data generated by the software instructions actually representing physical or tangible objects. One example of this might be where the software steps central to the claim generates signals or data that represent virtual steps of a method for assembling a diagnostic product or doing a vial-by-vial comparison of each of a plurality of physical samples.[12] As another example, the signals or data might represent a photo mask used in a diagnostic method. Apposite is *Research Tech*.[13]

Further Clues about the Patentability of Diagnostic Methods Involving Chemical Action

In *Prometheus Laboratories,*[14] a decision handed down on December 17, 2010, the Federal Circuit was asked to decide whether a claim on a diagnostic method is patentable subject matter under 35 U.S.C. § 101. The case was before the Federal Circuit on remand, the Supreme Court having vacated the Federal Circuit's earlier decision on June 29, 2010, in light of *Bilski*.[15] The diagnostic method in question pertained to a series of steps for optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder. The Federal Circuit had previously reversed the lower court grant of summary judgment of invalidity of 6,355,623 and 6,680,302 under 35 U.S.C. §101; confirming that the treatment method claims at issue were patent-eligible because the steps of administering a drug to a human body and determining the level of the drug's metabolite in the body each involved a transformation that satisfied the machine-or-transformation test. On remand, the Federal Circuit again held that *Prometheus'* asserted method claims recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations.[16]

In reversing the district court, the Federal Circuit explained that "[i]n light of the Supreme Court's decision in *Bilski*, patent eligibility in this case turns on whether Prometheus's asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use."[17] The court then went on to find that the inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of steps comprising particular methods of treatments. As the court observed, "[o]ther drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.[18]

Had the court ended its analysis there, *Prometheus* likely would go down as an unremarkable decision. However, the court's analysis did not end there. Instead, the court returned to the transformation test it had used in its pre-*Bilski* decision in explaining that "[i]t is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter."[19] "The transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined."[20] By doing so, the federal circuit may have signaled its intention to *go back* to the transformation test *to get to the future* of the subject matter patent eligibility of diagnostic method claims involving *a chemical action*. If *stare decisis* continues along these lines, the Supreme Court precedent would appear to support it.

The diagnostic step of "administering a drug [to a human body]" in *Prometheus* is not unlike the step of "adding chemical A to chemical B" in a chemical process, which is a conventional recitation in a chemical process patent. In this example, the "drug" is to "chemical A" as the "human body" is to "chemical B," *i.e.*, drug:chemical A::human body::chemical B. Similarly, the step of "determining the level of [the drug's metabolite in the body]" is not unlike "determining the level of (*e.g.*) acidity of a solution," which is another conventional recitation in a chemical process patent, *i.e.*, "determining level of drug:determining level of (*e.g.*) acidity::body:(*e.g.*) acidity. When viewed in this way, as appears was done by the Federal Circuit in *Prometheus*, the diagnostic method claims at issue arguably become no different than subject matter patentable eligible *chemical process claims* of the kind the Supreme Court has left undisturbed.

The Supreme Court thinking on subject matter patentability of chemical process patents is evident in *Cochrane v. Badishe* involving a reissued patent on a product-by-process claim.[21] Although not before the Court, the issue of subject matter patentability of the process claim was obliquely addressed by the Court when the Court explained that "another view of the case" is that patentability of the claim lies in the *process* for making the product and not in the product. The claim in the reissued patent recited: "artificial alizarine, produced from anthracene or its derivatives, by either of the methods herein described, or by any other method which will produce a like result." Steps very familiar to chemical practitioners such as "adding one part A to one part B," "heating," "obtaining a C," "distilling," "cooling" were left undisturbed by the Supreme Court in its subject matter patentable eligibility discussion.

In *Tilghman v. Proctor*[22] the chemical process claim recited generally: "*the manufacturing of fat acids and glycerin from fatty bodies by the action of water at a high temperature and pressure."* Steps also very familiar to chemical practitioners such as "manufacturing A and B from C," "by the action of water," "at a high temperature and pressure," were also left untouched by the Supreme Court as to subject matter patentable eligibility.

Both product and process claims were before the Supreme Court in *American Fruit Growers v. Brogdex Co.*[23] The Court held the product claims to be not patentable subject matter but set aside the process claims as anticipated. The process claim recited:

> 3. In the preparation of fresh fruit for market, the process which comprises subjecting fruit to the action of an aqueous solution of borax, the fluidity, strength and temperature of the treating solution, and the duration of the treatment, being such that exposed rind or skin tissues of the fruit are effectively impregnated with borax and rendered resistant to blue mold decay, while at the same time the fruit is not scalded nor is its freshness or edibility otherwise substantially impaired."

Steps very familiar to chemical practitioners such as "subjecting A to the action of B," "the fluidity, strength and temperature of B being" were left untouched by the Supreme Court as to subject matter patentable eligibility. Rather, the Court held those process claims to be anticipated.

Finally, in *Diehr,*[24] one of the trilogy of cases that along with the definition of Section 100(b) the *Bilski* Court points to for guidance on what constitutes patentable subject patent matter, the Court pointed to the following Supreme Court precedent in explaining that a physical and chemical process for molding precision synthetic rubber products falls within the Section 101 categories of patentable subject matter.

> A manufacturing process is clearly an art within the meaning of the law. Goodyear's patent was for

a process, namely, the process of vulcanizing india rubber by subjecting it to a high degree of heat when mixed with sulphur and a mineral salt."[25]

The term machine includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. *But where the result or effect is produced by chemical action, by the operation or application of some element or power of nature, or of one substance to another, such modes, methods, or operations are called processes*. A new process is usually the result of discovery; a machine, of invention. The arts of tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores, and numerous others are usually carried on by processes, as distinguished from machines. One may discover a new and useful *improvement in the process of tanning, dyeing,* &c. irrespective of any particular form of machinery or mechanical device. And another may invent a labor-saving machine by which this operation or process may be performed, and each may be entitled to his patent. *As, for instance, A has discovered that, by exposing India rubber to a certain degree of heat, in mixture or connection with certain metalic salts, he can produce a valuable product, or manufacture; he is entitled to a patent for his discovery*, as a process or improvement in the art, irrespective of any machine or mechanical device. B, on the contrary, may invent a new furnace or stove, or steam apparatus, by which this process may be carried on with much saving of labor and expense of fuel, and he will be entitled to a patent for his machine as an improvement in the art. Yet A could not have a patent for a machine, or B for a process; but each would have a patent for the means or method of producing a certain result, or effect, and not for the result or effect produced. It is for the discovery or invention of some practical method or means of producing a beneficial result or effect that a patent is granted, and not for the result or effect itself. It is when the term process is used to represent the means or method of producing a result that it is patentable, and it will include all methods or means which are not effected by mechanism or mechanical combinations.[26] (emphasis added)

In so doing, the Supreme Court recognized the subject matter patentability of chemical process patents based on process steps very familiar to chemical practitioners such as "subjecting A to a high temperature," "mixing A and B and C" as in the Goodyear patent for making rubber.

On the foregoing Supreme Court precedent, a diagnostic method that recites a chemical process step that is central to the claim should be treated, with respect to subject matter patentability, no differently from a chemical process patent. Just as the clue to the patentability of a chemical process patent is a chemical transformation, so too the clue to the patentability of diagnostic method claims involving a chemical action central to the claim should be a "transformation." That may be the direction the Federal Circuit may be taking when the *Prometheus* court went *back* to the transformation test *to get to the future* of how to determine the subject matter eligibility of diagnostic method claims that involve *a chemical action*.

Further Clues about the Patentability of Diagnostic Methods Involving Mechanical Action

On similar Supreme Court precedent, a diagnostic method that recites a mechanical process step that is central to the claim should be treated, with respect to subject matter patentability, no differently from a mechanical process patent.

The Supreme Court thinking on subject matter patentability of mechanical process patents is evident in *Expanded Metal Co. v. Bradford*[27] involving a patent on a process for expanding metal. The claim recited:

> The herein-described method of making open or reticulated metal work, which consists in simultaneously *slitting and bending* portions of a plate or sheet of metal in such manner as to stretch or elongate the bars connecting the slit portions and body of the sheet or plate, and *then similarly slitting and bending in places alternate to the first-mentioned portions*, thus producing the finished expanded sheet metal of the same length as that of the original sheet or plate, substantially as described. (emphasis added)

Steps very familiar to mechanical practitioners such as "slitting and bending," "alternately slitting and bending" were left untouched by the Supreme Court as to subject matter patentable eligibility.

In *Smith v. Snow*,[28] the Supreme Court upheld the validity of process claims involving setting eggs in staged incubation and applying mechanically circulated currents of air to the eggs. The claims recited:

1. The method of hatching a plurality of eggs
2. by *arranging them at different levels* in a closed chamber having restricted openings of sufficient capacity for the escape of foul air without undue loss of moisture and
3. *applying a current of heated air*, said current being created by means other than variations of temperature

and of sufficient velocity to circulate, diffuse, and maintain the air throughout the chamber at substantially the same temperature,

4. whereby the air will be vitalized, the moisture conserved, and the units of heat will be carried from the eggs in the more advanced stage of incubation to those in a less advanced stage for the purpose specified." (emphasis added)

Steps very familiar to mechanical practitioners such as "arranging them" and "applying a current of heat" were left undisturbed by the Supreme Court in its subject matter patentable eligibility discussion.

Just as the clue to the patentability of a mechanical process patent would appear to be a mechanical transformation, so too the clue to the patentability of diagnostic method claims involving a mechanical process central to the claim should be a "transformation."

Further Clues about the Patentability of Diagnostic Methods Involving Electrical Action

On similar Supreme Court precedent, a diagnostic method that recites an electrical process step that is central to the claim should be treated, with respect to subject matter patentability, no differently from a mechanical process patent.

The Supreme Court thinking on subject matter patentability of electrical process patents is evident in *The Telephone Cases*[29] involving a patent on the telephone. Alexander Bell's 3rd through 5th claims of his Letters Patent No. 174,465 before the Court recited: [30]

> 3. The method of *producing undulations* in a continuous voltaic current by the vibration or motion of bodies capable of inductive action, or by the vibration or motion of the conducting wire itself, in the neighborhood of such bodies, as set forth.
>
> 4. The method of *producing undulations* in a continuous voltaic circuit by gradually increasing and diminishing the resistance of the circuit, or by gradually increasing and diminishing the power of the battery, as set forth.
>
> 5. The method of and apparatus for *transmitting vocal or other sounds* telegraphically, as herein described, by *causing electrical undulations* similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth.

In examining these patents, the Supreme Court found "no well-founded objection to the right of Alexander Bell to these inventions."[31] In other words, the third through fifth claims recited patentable subject matter.

Steps very familiar to electrical practitioners such as "producing [undulations]," "transmitting [vocal or other sounds]," and "causing electrical [undulations "were left untouched by the Supreme Court as to subject matter patentable eligibility.

Just as the clue to the patentability of an electrical process patent would appear to be an electrically induced transformation, so too the clue to the patentability of diagnostic method claims involving an electrical process central to the claim should be a "transformation."

The Clue to the Patentability of Diagnostic Method Claims Involving a Chemical, Mechanical, or Electrical Process Step May Be to Craft Steps Central to the Claim Using Conventional Process Language

The clue to the subject matter patentability of diagnostic method claims involving a chemical process, a mechanical process, or an electrical process step that is central to the claim may be to craft those steps using conventional chemical process, mechanical process, or electrical process language. This would appear to be confirmed by the Supreme Court precedent that suggests that the transformation test remains a useful, albeit non-exclusive tool for avoiding preemption of a fundamental principle, a law of nature, or a physical phenomena.

Prometheus Laboratories Involves a Chemical Transformation

In *Prometheus Labs*[32] the claims recited:

> [A] method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> 1. administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
> 2. 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 8x108 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 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

On June 29, 2010, the Court granted certiorari, vacated the Federal Circuit's decision, and remanded, in light of *Bilski.*[33]

As the Federal Circuit held on remand, the claims do not preempt a fundamental principle because they involve a transformation. As explained by the Federal Circuit, determining the levels of 6-TG or 6-MMP in a subject necessarily [also] involves a transformation, for those levels cannot be determined by mere inspection. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus's expert, "at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue."[34] The Federal Circuit also stated that a further requirement for patent-eligibility is ensuring that the involvement of the transformation in Prometheus's claimed process is "not merely insignificant extra-solution activity."[35] The court found that the administering and determining steps are transformative and are central to the claims rather than merely insignificant extra-solution activity. The Federal Circuit previously confirmed that the treatment method claims at issue were patent-eligible because the steps of administering a drug to a human body and determining the level of the drug's metabolite in the body each involved a transformation.

We believe the court's holding of the claim to be patentable subject matter to be faithful to the Supreme Court's concern that a claim not preempt a fundamental principle, a law of nature, or a physical phenomena because the "administering" step alone, which is central to the claim, transforms the blood of a subject, which makes the "administering" step no different than a chemical process recitation. As to the "determining", we believe that the patent holder had the good fortune to have the benefit of a favorable construction of the term when the court construed the "determining" limitation to require spectroscopy or other physical methods. With this favorable claim construction, the "determining" step, like the "administering" step, was no different than a chemical process recitation.

In addition to pointing to a "transformation" as a clue to the patentability of a diagnostic method that is analogous to a chemical process, *Prometheus* also provides a valuable lesson to companies. Do not rely on a court to provide a favorable construction on terms such as "determining" because if the construction is unfavorable, you may be left with unpatentable subject matter.

Prometheus Laboratories may stand for the proposition that a diagnostic method that involves a step central to the claim that is transformative such as determining levels of chemistry by other than inspection and the transformation of human blood sample to no longer be human tissue is patentable subject matter.

Lab Corp Involves a Chemical Transformation

In *Lab Corp,*[36] the claims recited:

> a method for detecting a deficiency of cobalamin orfolate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

The Federal Circuit found Lab Corp liable for infringement of the patent because doctors, because of their training, would know that a normal homocysteinerange in blood is between 7 and 22 μmol/L (and in urine between 1 and 20 μmol/L).

The Supreme Court granted a petition for certiorari on claims upheld by the Federal Circuit but the Court later dismissed the petition as improvidently granted on procedural grounds because the Federal Circuit had not directly considered the 101 question. In his dissent of the certiorari denial Justice Breyer stated that the category of non-patentable "phenomena of nature," like the categories of "mental processes," and "abstract intellectual concepts," is not easy to define.[37]

However, we believe that the diagnostic step of "assaying a body fluid" in *Lab Corp* is not unlike the step of "analyzing a chemical a solution" in a chemical process, which is a conventional recitation in a chemical process patent. In this example, the "body" is to "solution," *i.e.*, body:solution). When viewed in this way, the diagnostic method claims at issue in *Lab Corp* arguably become no different from subject matter patentable eligible chemical process claims of the kind the Supreme Court has left undisturbed. On the other hand, we believe that the diagnostic step of "correlating an elevated level of total homocysteine" is not unlike the step of "looking at a beaker of a solution to observe a correlation." In the absence of a chemical transformation the "correlating" step becomes no more than an observation based on scientific principles that would amount to a preemption of a fundamental principle and so be unpatentable subject matter. The subject matter patentability of the *Lab Corp* claim

thus turns on the "assaying" step which is a chemical transformation and whether that transformation is central to the claim; which we believe it is.

The take-away for companies from *Lab Corp* once again is, as it was in *Prometheus*, to be sure to limit one or more central steps in your claim in a way that the step includes a transformation. As a step that is transformative, the claim arguably becomes no different than a transformative chemical, electrical, or mechanical process claim of the kind the Supreme Court have consistently left undisturbed.

On a final note on *Lab Corp*, we believe that the appropriate type of challenge to the *Lab Corp* claim should be based on Sections 102, 103, etc. and not on Section 101; given that the Lab Corp claim appears to have satisfied the Section 101 threshold by the recitation of the transformative "assaying" step, a step central to the claim.

Classen Involves a Chemical Transformation

In *Classen, t*he Federal Circuit applied the machine-or-transformation test in a biotechnology context, upholding a patent on a method for improving an immunization schedule involving method claims directed to identifying a safe vaccine regimen and involving a step of immunizing mammals. The claim recited:

> a method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises.
>
> 1. immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and
> 2. comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

In a nonprecedential disposition decided on December 19, 2008, the Federal Circuit affirmed the district court's grant of summary judgment that the claims are invalid under 35 U.S.C. §101.[38] The Federal Circuit held that "Dr. Classen's claims are neither 'tied to a particular machine or apparatus' nor do they 'transform a particular article into a different state or thing'" citing *Bilski*.[39] On June 29, 2010, the Court granted certiorari, vacated the Federal Circuit's decision, and remanded, in light of *Bilski.*[40] The Federal Circuit is yet to hear the remand.

We believe that the "immunizing" step in *Classen* is not unlike the "administering" step of *Prometheus* which the Federal Circuit found to be transformative. How the "comparing" step fares, however, on remand will depend on whether the step is construed to require some form of manipulation, such as a high pressure liquid chromatography method or other modification of the substances to be measured as was the case with the "determining" step in *Prometheus Laboratories*. If the "comparing" step requires no more than a visual observation, then the step becomes no different than the "comparing" step in *Lab Corp* and so is likely to be unpatentable subject matter. Regardless how the "comparing" step fares on the issue of transformation, however, we believe that the "immunizing" step in *Classen* is central to the claim and so the Classen claim is likely patentable subject matter. Having passed through the Section 101 gateway of patentable subject matter, we believe that the appropriate type of challenges to the *Classen* claim should be based on Sections 102, 103, etc. where the claims may very likely fail. In this regard, the claims are reminiscent of well known fundamental steps used in medical research: to wit, setting up a control group and a study group; immunizing the study group; and then comparing the results to the control group. This is how medical research is done.[41]

Myriad and Isolated DNA—If Not Markedly Different from Natural DNA Then Isolated DNA May Not Be Patentable

In *Association For Molecular Pathology v. U.S.P.T.O and Myriad Genetics,*[42] a decision handed down on March 29, 2010, the US District Court for the District of New York was asked to decide whether isolated DNA[43] containing naturally-occurring human BRCA½ gene sequences linked to breast and ovarian cancer, on which the US Patent and Trademark Office (USPTO) issued a patent in accordance with their practice of granting patents on DNA sequences so long as those sequences are claimed in the form of "isolated DNA," constitutes patentable subject matter under 35 U.S.C. §101. In granting Plaintiff's summary judgment of invalidity, the Southern District of New York held that 15 claims contained in seven patents issued by the USPTO to Myriad Genetics directed to "isolated DNA" containing sequences found in nature are unpatentable subject matter under 35 U.S.C. §101. [44] *As to the isolated DNA claims*, according to the Court, in light of DNA's unique qualities as a physical embodiment of

information, the isolated DNA claimed by the patented processes simply does not possess "markedly different characteristics" from a product of nature the Court found.[45] The information encoded by DNA reflects its primary biological function of directing the synthesis of other molecules in the body, DNA and so its ordering of the nucleotides serve as the physical embodiment of laws of nature, *i.e.*, those that define the construction of the body.[46] As to the *method claims*, they too were invalid under 35 USC §101 with the Court citing to [Federal Circuit] *Bilski.*

The court construed the method claims in the Myriad patents to be the abstract mental processes of "comparing" or "analyzing" gene sequences."[47] How these claims ultimately fare on appeal through the prism of *Bilski* likely will turn on whether the "comparing" or "analyzing" steps have been properly construed to cover "eyeball" inspection as was done by the court. If, as in *Prometheus*, the comparison requires more than an "eyeball" inspection such as manipulative techniques such as high pressure liquid chromatography methods then the term may not be the insignificant post solution activity as was found by the court.

In holding that the claimed isolated DNA was deemed to be not "markedly different" from native DNA the court reasoned that the utility of DNA is derived entirely from the information inherent in its nucleotide sequence and that isolated DNA in that respect merely mimics the information of natural DNA. The court acknowledged that the isolation of DNA removes it from the complex arrangement of chromosomal proteins (*i.e.*, chromatin) in which it is integrated in vivo but found that isolated DNA is not "markedly different" from natural DNA because both isolated and natural DNA share the same information content.

The issue in *Myriad* turns on the "new" prong of the "new and useful" requirement of Section 101. Those in favor of patentability of isolated DNA are arguing that the isolated DNA is "new," *i.e.*, not occurring in nature, and should be patentable subject matter just as was the genetically engineered microorganisms in *Charkabarty*. In *Charkrabarty*, the Court held that a genetically engineered microorganism useful for digesting oil spills was patentable manufacture or composition of matter under Section 101. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under Section 101.[48] There is some validity to their claims since "isolated DNA" does not exist in an isolated form in nature. Less problematic than isolated DNA are DNA molecules that are engineered by humans, including cDNAs as some of the claims in Myriad are limited, which would appear to be patentable subject matter. So too could be vectors, recombinant plasmits, chieric proteins, and similar fruits of the manipulation of genetic material which would not be nature's handiwork but man's which makes it not unlike the manipulation of microorganismsin Charrabarty which were found to be patentable.

Those opposed to patentability of isolated DNA contend that the isolated DNA is NOT new. The claims directed to unmodified genomic DNA are a product of nature and not invented. There is some validity to their claims too. The isolated DNA molecules would appear to have the same chemical structure and function but have been extricated from the natural cellular environment. The "isolated" limitation would appear to carry the entire weight of these claims. See *Funk* (isolated bacteria that exhibited valuable and previously unknown qualities in their isolated state not patentable).[49] See also isolation of lithium in metallic form; isolation of a single electron free of the atom not patentable.[50]

The reply of some patentability proponents allege a lack of appreciation that isolated DNA is functionally and structurally different from its natural form in vivo. It is the complex of DNA and chromosomal proteins within a cell that determines whether the information content is used. The complex three-dimensional architecture of natural DNA and proteins determines whether a gene is turned on or off and how frequently the gene is transcribed into mRNA. The structure of the DNA/protein complex is integral to its function. In other words, natural DNA would have no protein-encoding information to impart if it were to exist outside chromatin.

Some Supreme Court precedent may suggest a different view. In *Cochrane v. Badische Anilin & Soda Fabrik* the plaintiff obtained a patent for a process of artificially manufacturing alizarine, a red dye that naturally occurs in the root of the madder plant, and for the artificial alizarine (identirical to natural alizarine) that was the result of the claimed process. In upholding the process claim but rejecting the patentee's claim for the alizarine compound itself, the Supreme Court explained that

> [w]hile a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially, for the first time . . . .".[51]

Under this line of thinking, calling the DNA "isolated" does not make it a new composition. It is and always will be DNA.

Another Supreme Court precedent that may provide a clue to resolving this issue may be *American Wood-Paper Co. v. The Fibre Disintegrating Co.*[52] where the Court explained that:

> There are many things well known and valuable in medicine or in the arts which may be extracted from diverse substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture. It may have been in existence and in common use before the new means of obtaining it was invented, and possibly before it was known that it could be extracted from the subject to which the new process is applied. Thus, if one should discover a mode or contrive a process by which prussic acid could be obtained from a subject in which it is not now known to exist, he might have a patent for his process, but not for prussic acid. If, then, the Watt & Burgess patent for a product is sustainable it must be because the product claimed, namely, 'a pulp suitable for the manufacture of paper, made from wood or other vegetable substances,' was unknown prior to their alleged invention. But we think it is shown satisfactorily that it had been produced and used in the manufacture of paper long before 1853, the year in which the original patent of Watt & Burgess was dated.

Despite some ambiguity by the Court's use of language at the end of the cite concerning the production and use of pulp in the manufacture of paper long before 1853 (which suggests a Section 102 analysis), the examples used by the Court that a medicinal extract does not make the thing itself a new manufacture is a compelling statement that is pretty much on point in our view.

Section 101 makes clear that the product must be "new and useful" to be patentable subject matter. Man-made biotech products such as cDNA, etc. are man-made products and so likely patentable. Isolated DNA that is the stripped down form of DNA as it exists in nature in our view is probably not.

Suggested Strategies for Claiming Diagnostic Methods Post-*Bilski*

In order to distill the foregoing analysis into a suggested strategy for drafting claims on diagnostic methods in the unsettled aftermath of the *Bilski* decision and to assist practitioners, the following claim drafting tips are provided:

1. Strictly scrutinize recited steps that are central to the invention. Steps that recite "Information only" will not carry the day. Steps that recite a manipulation or modification of a substance or thing likely increases Section 101 patentability. Be sure central steps are not laws of nature, natural phenomena, or abstract ideas in order to comply with *Bilski* and that they do not entirely preempt the use of these things in order to comply with *Bilski*. Avoid steps that cover comparisons made by "eye-balling" the data. Craft recited steps central to *the in*vention and involving chemical, mechanical, or electrical action, with *the t*ype of language reserved for chemical, mechanical, and electrical process patents, respectively.
2. Craft recited diagnostic method steps involving software central to the invention by linking computer architecture to a physical or tangible object where possible. The link may be a physical link to the physical or tangible object *a la Diehr* or a *virtual link* to the data representing physical and tangible objects through computer architecture.
3. Introduce claims of differing scope with intermediate and narrow claims introducing into steps even more specificity in the transformation or, if a diagnostic method involving software, more significant physical or virtual links to physical or tangible objects.
4. For product claims, the product must satisfy the "new" prong of the "new and useful" requirement of Section 101.
5. Use the foregoing principles in prosecution and when construing issued claims in counseling, monetization, and litigation.

Conclusion

In *Bilski*, The Supreme Court affirmed the judgment of the Federal Circuit in rejecting the Bilski patent claims but under the Court's precedents on the unpatentability of abstract ideas and not on the machine-or-transformation test adopted by the Federal Circuit. In the aftermath of *Bilski*, now more than ever, practitioners need to understand what structure in a process and/or what process step amounts to an insignificant post solution activity or a token use of technology since patentability of a claim cannot be based on such structure and process steps. For diagnostic method patents involving chemical action, claim recitations central to the invention should recite determining chemical levels by other than visual inspection and not rely on naturally occurring samples for patentability; rather reciting transformation of biological or chemical samples. For diagnostic methods employing software, claim recitations central to the invention should physically or *virtually* reach out and touch a physical or tangible object.

1 Part 1 appeared in *IP Litigator*, Vol. 16, No. 5, September/October 2010.
2 *In re Bilski*, No. 08-964, slip op. (S.Ct. Jun. 10, 2010); 561 U.S. __ (2010).
3 Part 2 appeared in *IP Litigator*, Vol. 17, No. 1, January/February 2011.
4 Diamond v. Diehr, 450 U. S. 175, 192 (1981).
5 *See* Bilski, *supra*, at 6 in connection with discussing three exceptions to the patentability of subject matter, towit, "laws of nature, physical phenomena, and abstract ideas.
6 *Id.*, at 186; Parker v. Flook, 437 U.S.584, 590 (1978); and Gottshalk v. Benson, 409 U.S. 63, 68 (1972) ("[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Citing* 55 U.S. 175 (1853). *Diehr* in finding that insignificant post-solution activity cannot transform an unpatentable principle into a patent process, *Id.* at 192–193; *Flook* in finding the line between a patentable "process" and an unpatentable "principle" to be not always clear, *Id.* at 590; and *Benson*, in concluding that the process application sought to patent the mathematical formula, an idea, and in practical effect would be a patent on the algorithm itself, *Id.* at 71–72.
7 The signals or change in state that in turn touches the physical or tangible object can be electrical, optical, atomic, etc. as determined by the data.
8 In holding the claim in *Diehr* patentable, the Supreme Court found the Diehr "transformation" of the products by the claim steps significant explaining that "we think that a physical and chemical process for molding precision synthetic rubber products falls within the Section 101 categories of possibly patentable subject matter. That respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed. The respondents' claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure." *Diehr* at 70, citing *Cochrane v. Deener* for the legal principle that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." Cochrane v. Deener, 94 U.S. 787 (1877). In *Diehr*, the transformation of the product occurred because of the link of the software to the physical and tangible product. (*i.e.*, the "reaching out and touching" by the electrical signals generated by the software of physical and tangible objects.) As discussed in Part 2, Section 1 of this Article series, the "reaching out and touching" by the electrical signals generated by the software of physical and tangible objects *virtually,* that is to say, by electrical signals generated by the software instructions representing physical and tangible objects, also may give rise to patentable subject matter. See, for example, *Benson* on which the *Diehr* Court relies which rejected the notion that a process patent must be tied to a particular machine or apparatus or must operate to change articles or materials to a "different state or thing." As the Court in *Bilski* explained the machine-or-transformation test was never intended to be exhaustive or exclusive. Slip Op. p. 8, citing *Flook*, 437 U.S. 584, 588, n. 9.
9 *See* O'Reilly v. Morse, 56 U.S. 62, 82 (1853). Morse described his fifth claim as "[a] dictionary or vocabulary of words, numbered and adapted to this system of telegraph."
10 Research Corp. Techs. v. Microsoft Corp., No. CV-01-658, 2009 WL 2413623. (D. Ariz. July 28, 2009).
11 On December 8, 2010, the Federal Circuit upheld the patentability of claims that merely "assembl[ed] … gray scale images to generate final dot profiles" but that were not transformative because they did not "mandate a further visual display or image;" under arguably yet a new standard for determining the eligibility of software processes for patent – to wit, a "functional and palpable applications" test. *See* Research Corp. v. Microsoft Corp. appeal, p. 15. (Fed. Cir. 2010).
12 *See* Abstrax, Inc. v. Dell, Inc., No. 2:07-CV-221-DF-CE, 2009 WL 3255085, at *2 (E.D. Tex. Oct. 7, 2009).
13 *See*, *e.g.*, *Research Corp. Techs. v. Microsoft Corp.,* No. 2010-1037, slip op. (Fed. Cir. 2010); appeal from No. CV-01-658, 2009 WL 2413623. (D. Ariz. July 28, 2009).
14 Prometheus Laboratories, Inc. v. Mayo Collaborative Services, No. 08-1403, slip op. (Fed. Cir. 2010), *remand of* 581 F.3d 1336 (Fed. Cir. 2009) on which *cert. granted, judgment vacated, and remanded,* 78 U.S.L.W. 3254 (U.S. June 29, 2010).
15 *Id*.
16 *Id.* at 15.
17 *Id*. at 12–13.
18 *Id.* at 16.
19 *Id*. at 18, *citing Bilski*, 545 F.3d at 962.
20 *Id*.
21 Cochrane v. Badische, 111 U.S. 293 (1884) The patent reissued from 95,465 which was surrendered and actually reissued in two parts, one for a process for the production of artificial alizarine (RE 4,320) and the other for artificial alizarine produced by either of the methods described in the patent or by any other method producing a like result (RE 4,321). Only the reissued product-by-process claim recited in RE 4,321 was before the Court.
22 Tilghman v. Proctor, 102 U.S.707 (1880).
23 American Fruit Growers, Inc. v. Bogdex Co., 283 U.S. 1 (1931).
24 *Diehr*, 450 U. S. 175.
25 *Id.* at footnote 8.
26 *Id.* at footnote 7.
27 Expanded Metal Co. v. Bradford, 214 U.S. 336 (1972).
28 Smith v. Snow, 294 U.S. 1 (1935).
29 The Telephone Cases, 126 U.S. 1 (1988).
30 *Id.* at 14–15.
31 *Id.* at 112.
32 *Prometheus Labs*., 581 F.3d 1336.
33 Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 581 F.3d 1336 (Fed. Cir. 2009), *cert. granted, judgment vacated, and remanded,* 78 U.S.L.W. 3254 (U.S. June 29, 2010).
34 Prometheus Laboratories, Inc. v. Mayo Collaborative Services, slip op. (Fed. Cir. 2010).
35 *Bilski*, 545 F.3d at 962 (citing *Flook*, 437 U.S. at 590).
36 Lab Corp. of Am. Holdings (LabCorp) v. Metabolite Labs, Inc., 126 S. Ct. 2921, 2922–2923 (2006) (Breyer, J., dissenting).
37 *See Flook* at 589 ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear"). . . But this case is not at the boundary. . . . There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a "natural phenomenon."
38 *Classen Immunotherapies, Inc. v. Biogen IDEC, No*. 2006-1634, slip op. at 2 (Fed. Cir. Dec. 19, 2008), *cert. granted, judgment vacated, and remanded*, 78 U.S.L.W. 3680 (U.S. Jun. 29, 2010).
39 *Bilski*, 245 F.3d at 954.
40 Classen Immunotherapies, Inc. v. Biogen IDEC, 304 Fed. Appx. 866 (Fed. Cir. 2008), *cert. granted, judgment vacated, and remanded,* 78 U.S.L.W. 3680 (U.S. June 29, 2010).
41 It could be argued that that the "immunizing" step fails the "new" prong of the "new and useful" requirements of Section 101 since such immunization may occur by natural process when a mammal takes on disease. However, in this claim immunization is done with use of an immunigen and according to an immunization schedule. Hence, it does not appear to be a process existing in nature.
42 Association for Molecular Pathology v. U.S. Patent and Trademark Office, No. 09-cv-4515, slip op. (S.D.N.Y. Mar. 29, 2010, amended Apr. 5, 2010) (Sweet, J.), *appeal docketed*, No. 2010-1406 (Fed. Cir. June 22, 2010).
43 Isolated DNA is genomic material excised from an organism's genome and isolated from the cellular environment in which it naturally occurs, but without material change to its naturally occurring chemical structure and function.
44 *Id*. at 8.
45 *Id.* at 125.
46 *Id*. at 124.
47 *Id.* at 141.
48 *Charkabarty*, 447 U.S. at 310.
49 Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
50 *See also*, Ex parte Latimer, 46 O.G. 1638, 1889 Dec. Comm'r Patent 123 (1889) (fiber from needles of tree not patentable); Ex parte Berkman, 90 U.S.P.Q. 398 (1951) (physicologically active material derived from fresh raw plant material free of cellulosic material, electrolytes, enzymes not patentable.
51 Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293.
52 American Wood-Paper Co. v. The Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566 (1874).

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