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LAWS OF NATURE AND THE BUSINESS OF BIOTECHNOLOGY

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Abstract

The Supreme Court has shown an interest in the Intellectual Property area recently, particularly with respect to patentability under 35 U.S.C. §101. An appeal entitled LabCorp v. Metabolite *raised the product of nature exception to patentability, but this issue was not decided by the full court. To understand what may happen in a similar appeal, the present article reviews what occurred in the* LabCorp *case, the relevant Supreme Court decisions that preceded it, and relevant case law that has arisen afterwards. This article also discusses the potential effect on biological and diagnostic claims that are already issued or pending.*

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I. INTRODUCTION

Since the beginning of patent systems, two basic criteria for the grant of patents have stood out. The first criteria is that an idea or an invention must be "new," "novel," "not obvious," have an "inventive step," or meet some other basic criteria for newness. The idea or invention must also have some "utility" or be useful in some manner. In addition, the idea or invention must fall within a basic category of inventions for which patent protection is available. Put differently, regardless of how excitingly "new" or how generally useful an idea or an invention may be, there are *some* ideas and inventions that society has determined simply are not patentable and which are therefore referred to as "off limits." An example of "off-limit" ideas in the United States is the discovery of new compounds that are found in nature.[1] The "off-limits" ideas were often basic principles, products, or observations found in nature and it was felt that patents should not be awarded for simply discovering them. These new ideas were determined by society to be off limits because, among other reasons, it was believed that you can get too much of a good thing. That is, while patents often help aid inventors to develop inventions and advance the art, there are some ideas that, in balance, would not be of benefit to society if covered by patents. The "off limit" invention category most recently addressed by the Supreme Court and of clear relevance to the biotechnology industry is the "law of nature" category.[2]

The purpose of this article is to review and discuss the law that will affect biological and diagnostic claims in this off limits area codified in 35 U.S.C. § 101. It is structured in several sections as

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1. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 132-33 (1854).

2. There is an entry level question that is *not* explored in this article, and normally not addressed by courts to date. Specifically, the question is "what is a law of nature"? This question is highly relevant, virtually imponderable at some level, and worthy of investigation on its own account. Entire books are written about the question and there are differing views. For example, on one end of the extreme is Albert Einstein, who points out that even the "laws of nature," such as the constancy of the speed of light, which may be frequently cited as models of a "law of nature," are actually not laws at some level. "[N]atural laws [referring to Newton's "laws"] claim validity only when an inertial system is taken as the basis of the space-time description. The principle of inertia and the principle of the constancy of the velocity of light are valid only with respect to an *inertial system* [which would be modified by the theories of relativity]." ALBERT EINSTEIN, RELATIVITY: THE SPECIAL AND THE GENERAL THEORY, 170-71 (Robert W. Lawson trans., Three Rivers Press 1961). Others take a less rigid view of a "law of nature." For example, it is open to question whether any of the claims at issue for the patents discussed herein are "laws of nature," or correlations that provide only general direction to a scientist or physician. This issue should be explored in any case as an entry point.

follows. The first section sets out the historical development for statutory subject matter using the early English case law and legislation and then discusses the decisional development in the United States until the early 1980s. The next section discusses a 2006 Supreme Court case that illustrates a biological and diagnostic context. Recent case law published thereafter is discussed in the following section then concludes with tests for statutory subject matter and how they may affect current claims.

35 U.S.C. § 101 provides the statutory basis for questions such as what constitutes a law of nature. This section provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[3]

II. ROOTS OF THE LAW OF NATURE IN BIOTECHNOLOGY

A. The Early Legal Principle

The early English system of patent law assumed that everything was an off-limit area of technology unless it was a "new manufacture."[4] In effect, a large amount of technology was in the off-limit area, including manufacturing techniques, and methods of operation.[5]

1. English Patent Cases

Early patent cases began to address the limits of patentable subject matter. For example, *Neilson v. Harford*,[6] in the English Court of the Exchequer, addressed the patentability of an improved application of heated air to produce heat in fires, forges and furnaces. The invention related to the idea that a forge or furnace operated better if the incoming air was pre-heated. The Court held:

> It is very difficult to distinguish [the invention] 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,

3. 35 U.S.C. §101 (2000).
4. English Statute of Monopolies of 1623, 21 Jac. 1, ch. 3, § 6.
5. Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (1836) (repealed 1870).
6. Neilson v. Harford, (1841) 151 Eng. Rep. 1266.

> we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one.[7]

The Court decided that the patent was not for a principle, but for a mode of carrying out the principle.[8] In effect, the Court struggled with the same issue with which courts struggle today – is a patent claiming the law of nature, i.e. the principle, or is the patent covering an invention in which the principle is applied to something new and patentable?

The Court decided that, while the principle that hot air will promote ignition of fuel better than cold air was embodied in the machine, the principle alone was not sufficient to support the patent. Instead it was supported because Neilson had applied the principle to invent a mechanical apparatus which could deliver a current of hot air instead of cold.[9]

2. Early Supreme Court Cases - A *Prior Art* Approach

An early case in the United States dealt with the patentable subject matter question in the context of a method claim. In *Le Roy v. Tatham*,[10] the Tatham brothers sued Thomas Le Roy and David Smith. for infringement of a patent for an improvement on the machinery of making lead pipes. The Court stated:

> *A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known.*[11]
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> . . . .
>
> . . . [T]he invention is not in discovering them, but in applying them to useful objects.[12]
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> . . . .
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> *. . . But the jury were instructed, 'that the originality of the invention did not consist in the novelty of the machinery, but in bringing a newly discovered principle into practical application.'*[13]

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7. *Id.* at 1273
8. *Id.*
9. *Id.*
10. Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1852).
11. *Id.* at 175 (emphasis added).
12. *Id.*

The Court said that the proper way to consider the patent claims was the *novelty of the combination of the parts* and not whether a newly developed property of lead might have been patented. However, the Court's previous statements, excerpted above, indicate that a newly developed property of lead would not have been patentable.[14]

3. *O'Reilly v. Morse* - A *Written Description* Approach

Samuel F.B. Morse sued Whitman and Hastings for infringing two of his patents on the telegraph (the 1840 and 1848 patents).[15] The Court found claim 8 of the 1840 patent was invalid and that the remaining claims were valid and infringed. Claim 8 read as follows: "[t]he combination and arrangement of electro-magnets, in one or more circuits of metallic conductors, with armatures of magnets, for transmitting intelligence by signs and sounds, or either, between distant points and to different points simultaneously."[16]

Neilson was cited for the premise that "the discovery of a principle in a natural philosophy or physical science, is not patentable."[17] The Court determined that Morse had "not discovered, that the electric or galvanic current will always print at a distance" and that electro-magnetism may be used as a motive power without printing at a distance.[18]

The Court held that claim 8 was overly broad and could "derive no aid from the specification filed."[19] It was drawn to any use of electro-magnetism "for making or printing intelligible characters, letters, or signs, at any distances"[20] and the patent was not limited "to the specific machinery, or parts of machinery described in the foregoing specifications and claims."[21]

The Court used terminology similar to a contemporary written description rejection, i.e., failure of the specification to describe what was covered by the language of claim 8. The Court stated "[f]or he [Morse] claims what he has not described in the manner required by law. And a patent for such a claim is strongly forbidden by the act of

13. *Id.* at 176-77 (emphasis added).
14. *Id.*
15. O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).
16. *Id.* at 78.
17. *Id.* at 116.
18. *Id.* at 117.
19. *Id.* at 119.
20. *Id.* at 86.
21. *Id.*

Congress."[22] Outside of the written description issues, *Morse* has been cited for the premise that one cannot patent a mere principle,[23] especially when a natural phenomenon is one of its few described elements.

Tilghman v. Proctor[24] follows up on the *Morse* decision. Richard Tilghman sued William Proctor and James Gamble (Proctor and Gamble) for infringement of U.S. Patent No. 11,766 (filed Oct. 3, 1854). Tilghman's patent claims a process of separating "fat acids and glycerin from fatty bodies by the action of water at a high temperature and pressure."[25] The Court found the patent valid and infringed. The single claim of the patent read as follows: "I claim, as of my invention, the manufacturing of fat acids and glycerin from fatty bodies by the action of water at a high temperature and pressure."[26]

This case is cited for the concept that a patent can be granted for a process, not just for machines and compositions of matter. However, the Court distinguished *Tilghman* from *Morse* as follows:

> Yet it has been supposed that the decision in O'Reilly v. Morse was adverse to patents for mere processes. The mistake has undoubtedly arisen from confounding a patent for a process with a patent for a mere principle . . . . The eighth claim of Morse's patent was held to be invalid, because it was regarded by the court as being not for a process, but for a mere principle.[27]

The *Tilghman* Court viewed Morse's claim 8 as being invalid since it was a claim to the power of electro-magnetism itself, rather than a process of utilizing the power; "a claim put forward on the ground that the patentee was the first to discover that it *could* be thus employed."[28]

The *Tilghman* Court then quoted extensively from the *Morse* opinion in order to provide support for their interpretation of *Morse*.[29] While it is clear that *Morse* does not stand for the proposition that process claims are unpatentable, it is not clear that *Morse* stands for the premise cited in *Tilghman*. Arguably, the sections of *Morse* cited by the *Tilghman* court suggest that the real basis of the *Morse* opinion

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22. *Id.* at 120.
23. *See infra* note 24.
24. Tilghman v. Proctor, 102 U.S. 707 (1880).
25. *Id.* at 709.
26. *Id.*
27. *Id.* at 726.
28. *Id.* at 727.
29. *Id.* at 726-28.

was a lack of adequate written description rather than a claim to a mere principle.

4. An Early "Biotechnology Case" - Revisiting the Prior Art Approach *and* the Written Description Approach

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[30] the United States Supreme Court used the law of nature doctrine for the first time as an early underpinning for the biotechnology field. Kalo Inoculant sued Funk Brothers for infringement of U.S. Patent No. 2,200,532 (filed Aug. 24, 1938) which had claims to the product and process of making a mixed culture of root nodule bacteria for inoculating leguminous plants.[31] Funk Brothers counterclaimed that the patent was invalid. Only the patentability of the product claims was reviewed by the Court.[32]

The patent claims in Funk Brothers were directed to a plant inoculant made of several bacterial strains. Specifically,

> 1. An inoculant for leguminous plants comprising a plurality of selected cultures of different species of bacteria of the genus Rhizobium, one of said cultures being *Rhizobium trifolii alpha*, said cultures being substantially unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.[33]

Each of the strains was individually found in nature and beneficial to a particular plant. The proprietor of the patent, however, had combined them together so that a farmer could buy one inoculant for any of several plants rather than a particular inoculant for a particular plant.[34] The bacteria assist the plants in fixing nitrogen. Historically there were different groups of leguminous plants that could only be successfully inoculated by different species of bacteria specific for each group.[35] Previous mixed cultures of bacteria failed to work properly because the different species inhibited each other. Kalo Inoculant ascertained that mutually non-inhibitory strains existed. By certain methods of selection and testing they isolated them and

30. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
31. *Id.* at 130.
32. *Id.*
33. U.S. Patent No. 2,200,532 col.13 ll.22-29 (filed Aug. 24, 1938).
34. *Funk Bros.*, 333 U.S. at 129-30.
35. *Id.*. at 128-29.

developed a mixed culture that could be used equally well with multiple groups of leguminous plants.[36]

The Seventh Circuit thought that the inventor did more than discover a law of nature, since he had made a new and different composition of non-inhibitive strains that had utility in the manufacture of inoculants.[37] However, the Supreme Court was not persuaded, and held "[t]he 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."[38] The Court went on to state that the discovery was only in relation to the handiwork of nature and that the combination of species produces no new bacteria, no change in the species of bacteria and no enlargement of the range of utility.[39] The Court held that "a product must be more than new and useful to be patented; it *must also satisfy the requirements of invention or discovery.*"[40] The Court further stated that once the secret of the non-inhibitive quality of certain strains of bacteria had been discovered it was a simple step to produce a mixed inoculant that, while it may "have been the product of skill, it certainly was *not the product of invention.*"[41]

In his concurrence, Justice Frankfurter also concluded that the claims were not patentable, but on *written description or enablement grounds* rather than "work of nature" grounds.[42] In his view, the

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36. *Id.* at 129-30.

37. *Id.*

38. *Id.* at 130.

39. *Id.* at 131.

40. *Id.* at 131-32 (citations omitted) (emphasis added).

41. *Id.* at 132 (emphasis added).

42. *Id.* at 134-35 (Frankfurter, J., concurring). Justice Frankfurter also felt that rejections based on law of nature were difficult to apply.

> It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent. . . . . Multi-purpose tools, multivalent vaccines, vitamin complex composites, are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged. In finding Bond's patent invalid I have tried to avoid a formulation which, while it would in fact justify Bond's patent, would lay the basis for denying patentability to a large area within existing patent legislation.

Id. at 135 (Frankfurter, J., concurring).

packaging of a mixture of particular strains of bacteria is a patentable invention provided that the particular strains are identifiable and adequately identified.[43] He viewed the '532 patent as invalid since the inventor

> [A]ppears to claim that since he was the originator of the idea that there might be mutually compatible strains and had practically demonstrated that some strains exist, everyone else is forbidden to use a combination of strains whether they are or are not identical with the combinations that [the inventor] selected and packaged together.[44]

One possible implication of the majority's opinion is that regardless of the time, effort and ingenuity involved in discovering new attributes about living organisms, they are not patentable unless they are changed from their natural state (as there is no physical transformation). Further, aggregates of these bacteria are unpatentable since they are also unchanged from nature.

This holding also raises a question of whether the converse holds true: if aggregating things that exist in nature is not sufficient to render them patentable, is isolating something from nature equally insufficient? The patent office has placed a great deal of weight on the word "isolated" in DNA, particularly in the context of protein applications to differentiate claimed products from those found in nature. However, based on *Funk*, it would be plausible to argue that once the secrets of a DNA or protein sequence had been discovered, it would be a "simple step" to isolate them. Consequently, this would not be sufficient to qualify as a "product of invention".

B. Moving Beyond Novelty and Written Description

In *Gottshalk v. Benson*,[45] a suit was brought by Gary Benson against Robert Gottshalk, Acting Commissioner of Patents, over a rejection of claims directed to a method for converting signals from binary coded decimal form into pure binary numerals.[46] The Court framed the question as to whether the method described and claimed was a "process" within the meaning of the 35 U.S.C. § 101.[47] It was really a question of statutory subject matter.

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43. *Id.* at 133 (Frankfurter, J., concurring).
44. *Id.* at 133 (Frankfurter, J., concurring).
45. Gottshalk v. Benson, 409 U.S. 63 (1972).
46. *Id.* at 64.
47. *Id.*

After reviewing the case law that analyzes patentability for statutory subject matter, the Court simply held that an individual cannot patent an idea:

> 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. It is said that the decision precludes a patent for any program servicing a computer. We do not so hold. It is said that we have before us a program for a digital computer but extend our holding to programs for analog computers. We have, however, made clear from the start that we deal with a program only for digital computers. It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. Such is not our purpose. What we come down to in a nutshell is the following.
>
> It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself. [48]

The Court stated that Congress should address the issue of patentability of computer programs and that the Patent Office was not competent to search prior art for computer programs.[49] But the language of the decision expressly left the door open to patent technology that was not addressed by previous Supreme Court decisions.

In a subsequent case, *Parker v. Flook*,[50] a suit was brought by Dale Flook against Lutrelle Parker, Acting Commissioner of Patents, over a rejection of claims for calculating alarm limit values during catalytic conversion processes, in which the only novel feature was mathematical formula.[51] The issue confronting the Court was "whether the identification of a limited category of useful, though conventional, post-solution applications of such a [new mathematical]

48. *Id.* at 71-72.

49. *Id.*

50. Parker v. Flook, 437 U.S. 584 (1978).

51. *Id.* at 585.

formula makes respondent's method eligible for patent protection."[52] The Supreme Court assumed that the patent was novel and applied section 101 to answer the question above.[53] The plain language of section 101 did not provide a straightforward answer since the Court recognized that the "line between a patentable 'process' and an unpatentable 'principle' is not always clear."[54]

The Court held that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm."[55] Following *Mackay Radio & Telegraph Co. v. Radio Corp. of America*[56] and *Funk Bros.*, the Court determined that "[t]he process itself, not merely the mathematical algorithm, must be new and useful."[57]

In *Parker*, the Court sets out an analysis that can be described as follows: first, it must be determined if the algorithm or process recited in the claim is a law of nature that cannot be patented because it is not one of the kind of "'discoveries' that the statute was enacted to protect"; second, if the answer is determined to be yes, then the claim must be considered as if the algorithm is within the prior art;[58] and third, the claim must be examined to determine if there is some other inventive concept recited.[59] The Court seemed willing to allow claims that incorporate laws of nature if the claim is not otherwise limited to conventional elements. In other words, the claim cannot stand alone on a novel algorithm; some other element must be novel for the claim to survive.

The Court found that the algorithm was not sufficient to make an otherwise conventional method eligible for patent protection.[60] The dissent took the position that the Court was importing novelty and obviousness criteria into the section 101 analysis, which served merely to muddy the issue since these are on there face separate statutes with separate criteria.[61] However, *Flook* has not been overturned and is still good law.

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52. *Id.*
53. *Id.* at 588.
54. *Id.* at 589.
55. *Id.* at 590 (citations omitted).
56. MacKay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86 (1939).
57. *Flook*, 437 U.S. at 591.
58. *Id.* at 593-94.
59. *Id.* at 594.
60. *Id.*
61. *Id.* at 600 (Stewart, J., dissenting).

Diamond v. Diehr[62] was the last Supreme Court decision to address statutory subject matter prior to *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*,[63] and it continues to be one of the most important decisions discussed thereafter. James Diehr sued Sidney Diamond, Commissioner of Patents, based on a rejection of his process claims. The Court of Claims and Patent Appeals (CCPA) reversed. Certiorari was granted and Justice Rehnquist delivered the opinion of the Court.

The patent claimed a method of creating rubber products by molding rubber using heat and pressure.[64] One of the steps in the process also required monitoring the temperature and adjusting it using a computer program.[65] The patent office rejected the claim as the computer program was nonstatutory subject matter and the remainder of the claim was conventional.[66] The Board of Appeals agreed with the Examiner, but the CCPA reversed.[67]

The Supreme Court started its analysis by commenting on how it intended to read the statute: "[In] in dealing with the patent laws, we have more than once cautioned that 'courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'"'[68] These comments framed the scope of the analysis and showed that the Court has a more expansive interpretation of statutory subject matter.

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62. Diamond v. Diehr, 450 U.S. 175 (1981).

63. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006). *See infra* note 196.

64. *See Diehr*, 450 U.S. at 177.

> The claimed invention is a process for molding raw, uncured synthetic rubber into cured precision products. The process uses a mold for precisely shaping the uncured material under heat and pressure and then curing the synthetic rubber in the mold so that the product will retain its shape and be functionally operative after the molding is completed.

65. *Id.* at 178-179.

> Respondents characterize their contribution to the art to reside in the process of constantly measuring the actual temperature inside the mold. . . . [T]he continuous measuring of the temperature inside the mold cavity, the feeding of this information to a digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press, are all new in the art.

66. *Id.* at 179-180.

67. *Id.* at 181. The CCPA noted that a claim drawn to subject matter otherwise statutory does not become nonstatutory because a computer is involved. The respondents' claims were not directed to a mathematical algorithm or an improved method of calculation but rather recited an improved process for molding rubber articles by solving a practical problem that arose in the molding of rubber products.

68. *Id.* at 182 (citations omitted).

The *Diehr* Court considered the definition of a process and relied on *Cochrane v. Deener*[69] and *Gottshalk v. Benson*[70] to reemphasize 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."[71] The Court then determined that the process was directed to a step-by-step method for molding rubber, not a computer program.[72] It was not rendered unpatentable due to the presence of a computer program and a mathematical equation.[73]

The Court was also presented with the argument that the claim was unpatentable because nothing else in the claim was new besides the algorithm, which must be assumed to be prior art.[74] However, the Court stated that the claim must be analyzed as a whole:

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.[75]

The Court went on to explain that all inventions can be reduced to their underlying principles that will make their implementation obvious once they are known.[76]

The next issue was whether the claim was trying to cover the algorithm in the abstract.[77] The Court reiterated that the claim was a process for curing rubber and not an attempt to protect the algorithm itself.[78] The focus was on the elements that were recognized as patentable without the algorithm. The Court rejected the argument in *Flook* that the claim should be patentable because all possible uses of the algorithm were not preempted [79] At least one reason that the *Flook* claims were not patentable was because insignificant post-solution

69. Cochrane v. Deener, 94 U.S. 780 (1876).
70. Gottshalk v. Benson, 409 U.S. 63 (1972).
71. *Diehr*, 450 U.S. at 184 (citation omitted).
72. *Id.* at 192-93.
73. *Id.*
74. *Id.* at 189 n.12.
75. *Id.* at 188.
76. *Id.* at 189 n.12.
77. *Id.* at 191.
78. *Id.* at 192-93.
79. *Id.* at 193 n.14.

activity was not enough to make the claimed invention statutory subject matter.[80] Consequently, the Court clarified *Flook* and established a principle for determining what qualifies as statutory subject matter when a computer program or other potential exclusion to statutory subject matter was included in a claim.

C. Biotechnology Arrives

The classic first decision in biotechnology is *Diamond v. Chakrabarty*.[81] In that case, the Supreme Court determined that a live human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.[82] The claimed micro-organism was a bacterium that had been engineered with additional plasmids to aid in its ability to digest oil.

The Supreme Court distinguished the facts of *Chakrabarty* from *Funk Bros.* as follows: in *Funk*, the "patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other . . . Concluding that the patentee had discovered 'only some of the handiwork of nature,' the Court ruled the product nonpatentable."[83] Here, in contrast, the Court found that the patentee had "produced a new bacterium with markedly different characteristics from any found in nature . . . [h]is discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."[84]

The Court stated that the distinction for purposes of patentability under section 101 is "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[85] Further, the Court clarified *Flook* and stated that it did not "announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*."[86] The majority of the Court seemed to be persuaded that Chakrabarty's bacterium was patentable since it was new and different from natural bacteria.

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80. *Id.*
81. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
82. *Id.* at 318.
83. *Id.* at 310.
84. *Id.*
85. *Id.* at 313.
86. *Id.* at 315.

D. Application to Present Day Issues

The question of what qualifies as statutory subject matter received attention in Supreme Court decisions up to 1981, but became less important until the present day.[87] Recent decisions have brought this issue back to the attention of the Supreme Court, the Federal Circuit and the Patent Office. These decision-making bodies have often raised the issue *sua sponte* as a new rejection.[88]

The question of what qualifies as statutory subject matter applies irrespective of technology area, but has developed a focus in the biotechnology arts, the computer program and signal areas. The following text discusses the Supreme Court case that most recently addresses what is statutory subject matter in the biotechnology and diagnostic arena.

III, THE *LABCORP* LITIGATION

In 2005, the Supreme Court was poised to address the question of patentable subject matter for biological process claims when it granted certiorari in *Metabolite Labs., Inc. v. Laboratory. Corp. of America. Holdings.*[89] Ultimately, the case was left undecided, but rapid advances in the rate of medical discovery and the importance of patent protection for such discoveries make it likely that the issue of what qualifies as statutory subject matter in a biological process claim will be revisited. The following discussion starts with the facts and events leading to the appeal to the Supreme Court because the issues surrounding 35 U.S.C. § 101 were not discussed until the appeal arrived at the Supreme Court. Furthermore, the lack of development in the record was why the case was ultimately left undecided.

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87. The Supreme Court discussed whether plants could be the subject of utility patents in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124 (2001). 35 USC § 101 was addressed, but not in the manner discussed in the previous cases above.

88. *See* Peter Zura, "Waiting for Nuijten" - 101 Rejections at the BPAI (Part 1), Sept. 11, 2007, http://271patent.blogspot.com/2007/09/waiting-for-nuijten-101-rejections-at.html; Peter Zura, "Waiting for Nuijten" - 101 Rejections at the BPAI (Part 2), Sept. 12, 2007, http://271patent.blogspot.com/2007/09/waiting-for-nuijten-101-rejections-at_12.html. He reports that appeals of section 101 rejections at the Board of Patent Appeals and Interferences were at their lowest level in 2005 at 14 appeals, but that 2007 showed the highest level in recent history.

89. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

A. The District Court

The patent in suit, U.S. Patent No. 4,940,658 (filed Nov. 20, 1986), is entitled "Assay for sulfhydryl amino acids and methods for detecting and distinguishing cobalamin and folic acid deficiency". It was assigned to University Patents Inc. (UPI), who licensed it to Competitive Technologies Inc., and then to Metabolite.[90] Metabolite sublicensed the patent to Roche Biomedical Laboratories, which is now known as LabCorp.

Claims 1-12 are directed to a particular method for assaying the amount of one or more sulfhydryl amino acid species present in a given sample, an example of which is homocysteine.[91] The patentees also obtained claim 13, which covered a method for detecting a deficiency of cobalamin or folate in warm-blooded animals:

> 13. A method for detecting a deficiency of cobalamin or folate 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.[92]

Cobalamin and folate are both B vitamins, commonly known as B_{12} and folic acid. A deficiency in these vitamins can cause vascular disease, cognitive dysfunction, birth defects, and cancer, among other conditions.[93] The test was designed to identify individuals with these vitamin deficiencies, so that they could be treated with nutritional supplements.[94]

LabCorp had originally performed assays according to the method of claims 1-12, but changed to a new test obtained from Abbott Laboratories. LabCorp then stopped paying royalties to Metabolite, prompting the lawsuit.[95]

Metabolite filed the lawsuit against LabCorp in the United States District Court for the District of Colorado for breach of contract and

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90. *Id.* at 1359.

91. *See* U.S. Patent No. 4,940,658 col. 41 (filed July 10, 1990).

92. '658 Patent col. 41.

93. *Metabolite,* 370 F.3d at 1358

94. *Id.*. The Court also commented that the inventors discovered the relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate and a test for determining the level of homocysteine.

95. *Id.* at 1359.

infringement of the '658 patent.[96] At the end of the trial, the jury found that LabCorp infringed the '658 patent because "[t]he record shows that physicians order assays and correlate the results of those assays."[97] The Colorado District Court assessed damages for breach of contract and infringement (which were doubled for willfulness) and also issued a permanent injunction.[98]

B. The Federal Circuit

On appeal, LabCorp raised several issues. They sought a new construction of the term "correlating" in claim 13 and raised invalidity defenses based on anticipation, obviousness, indefiniteness, lack of written description and enablement.[99] LabCorp also argued that the claim only covered situations where the homocysteine levels actually were elevated (approximately 20% of cases), not all tests. However, LabCorp did not raise the issue of nonstatutory subject matter as an invalidity defense.

The Federal Circuit affirmed the District Court's claim construction of "correlating"[100] and rejected the arguments concerning indefiniteness, lack of written description, lack of enablement, anticipation and obviousness.[101] They also affirmed the holding of infringement[102] as they found that physicians ordered the tests and that LabCorp had encouraged or induced them to do so based on LabCorp publications that republished the correlation between the vitamin deficiency and the conditions.[103] The Court found that the physicians were direct infringers and that LabCorp induced their infringement.[104]

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96. *Id.* at 1359.

97. Brief for the United States as Amicus Curiae at 3, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607) [hereinafter Solicitor General Brief I]. For a discussion of split or joint infringement of patent claims, see BMC Res., Inc. v. Paymentech, L.P., No. 2006-1503, 2007 WL 2728400 (Fed. Cir. (Tex.) Sept. 20, 2007); PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342 (Fed. Cir. 2007); Free Standing Stuffer, Inc. v. Holly Dev Co., No. 72 C 1070, 1974 WL 20219 (N.D. Ill. Dec. 24, 1974); Shields v. Halliburton Co., 493 F. Supp. 1376 (W.D. La. 1980); Sriranga Veeraraghavan, *Joint Infringement of Patent Claims: Advice for Patentees*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 211 (2006).

98. *Metabolite*, 370 F.3d at 1359.

99. *Id.* at 1361,1365-66; *see also* Solicitor General Brief I, *supra* note 97, at 4.

100. *Metabolite,* 370 F.3d at 1361 (correlating was interpreted to mean "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies).

101. *Id.* at 1366-68.

102. *Id.* at 1358.

103. *Id.* at 1365.

104. *Id.* at 1365.

The Court of Appeals denied rehearing and rehearing en banc on August 5, 2004.[105] Petitioner LabCorp then filed a request for Certiorari on November 3, 2004 that was ultimately granted.[106]

C. Supreme Court

On February 28, 2005 the Supreme Court changed the focus of the issues of the appeal and made the following request to the Solicitor General of the United States:

> The Acting Solicitor General is invited to file a brief in this case expressing the views of the United States limited to the following question: Respondent's patent claims a method for detecting a form of vitamin B deficiency, which focuses upon a correlation in the human body between elevated levels of certain amino acids and deficient levels of vitamin B. The method consists of the following: First, measure the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice whether the amino acid level is elevated and, if so, conclude that a vitamin B deficiency exists. Is the patent invalid because one cannot patent "laws of nature, natural phenomena, and abstract ideas"?[107]

In reply, the Solicitor General filed a brief on August 26, 2005, focusing on two main issues: (1) whether the facts were sufficiently developed in the lower courts to make a decision and, if so, (2) what was the relevant law surrounding the substantive issue of utility and the exceptions classified as "laws of nature, natural phenomenon, and abstract ideas."[108] The Supreme Court eventually decided to take the case on October 31, 2005 and the Solicitor General filed a second brief on December 23, 2005, with a discussion of additional issues.[109]

1. The Procedural Issue

The Solicitor General asserted that it was too late to raise the question of utility at this stage of the appeal as the issue had not been

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105. *Id.* at 1354.

106. *See* Petition for a Writ of Certiotari to the United States Court of Appeals for the Federal Circuit, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607) 2004 WL 2505526.

107. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 543 U.S. 1185 (2005) (citation omitted).

108. *See* Solicitor General Brief I, *supra* note 97, at 4, 5.

109. Brief for the United States as Amicus Curiae, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607) [hereinafter Solicitor General Brief II]. The two Solicitor General briefs overlap on the substantive issues.

raised or developed in either the District Court or the Federal Circuit.[110] Even though the issue was indirectly raised at the Federal Circuit oral argument, it was discussed in support of a different issue.[111] The lack of *inter partes* development affected the appeal because the District Court did not have the opportunity to consider various important factors in determining utility, such as the meaning of the term "assay"[112] or develop the record as to whether claim 13 covered all substantial applications of the method, both of which are important facts for consideration.[113] Respondent Metabolite may have argued for different claim interpretations of terms that were construed, such as "correlating", so that "assay" and "correlating" did not cover substantially all uses of a natural phenomenon.[114] The

110. *See* Solicitor General Brief I, *supra* note 97, at 15.

> 1. a. Petitioner did not challenge the validity of claim 13 under the natural phenomenon doctrine in either of the lower courts, and neither of those courts addressed the question. Indeed, petitioner did not mount any challenge, under any theory, to the patentability of the claimed subject matter under Section 101. Instead, petitioner argued that claim 13 is invalid for indefiniteness, lack of written description, lack of enablement, anticipation, and obviousness. Pet. Corr. C.A. Br. 38-52.

111. *See id.* at 15-16.

> In the court of appeals, petitioner did allude to the natural phenomenon argument in the course of arguing that claim 13 is indefinite because it does not describe the "correlation" step with sufficient specificity. Pet. Corr. C.A. Br. 41. In particular, petitioner noted in passing that if its indefiniteness challenge were rejected, respondent CTI "would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own. The law is settled that no such claim should be allowed." *Ibid.* (citing *Diehr*, 450 U.S. at 185). Petitioner advanced that cursory argument solely in support of its indefiniteness challenge, however, not as a separate challenge under Section § 101.

112. *See id.* at 9.

> Because petitioner did not argue below that claim 13 attempts to claim non-patentable subject matter and is therefore invalid under section 101 (see pp. 15-16, infra), the courts did not focus on the term "assay" or otherwise address claim 13 "as a whole." Indeed, the lower courts did not interpret the claim term "assay" at all. See Pet. App. 13a.

113. *See id.* at 10.

> The record is also not well developed on the question whether the process claimed in claim 13 comprises every "substantial practical application" of the natural relationship between elevated total homocysteine and deficiencies in the B vitamins. *See Benson*, 409 U.S. at 71-72; p. 8, *supra*. Indeed, there appears to be nothing in the record that directly addresses the question whether there are other practical applications that qualify as "substantial" within the meaning of *Benson*.

This discussion about "covering every substantial practical application" relates to process claims, not products. It is generally accepted that product claims cover all uses of the product.

114. *See id.* at 19.

Solicitor General went on to explain that the Supreme Court still had the discretion to hear the case, but should defer.[115] Any decision that would issue would likely have a significant impact on the biotech industry as thousands of patents had been issued by the PTO based on the understanding that this subject matter was patentable and the health care community had come to rely on this patent coverage.[116] There were substantial reasons for the relevant issues to be fully vetted before a decision. The Solicitor General concluded by saying, "[b]ut if this Court were to consider reevaluating almost a quarter-century of administrative practice and lower court jurisprudence, it should do so based on a full record in a case where the issue was properly raised, litigated, and decided below."[117]

On October 31, 2005, the Supreme Court granted the petition for certiorari only with respect to whether claim 13 was unpatentable because it fell within one of the three exceptions to statutory subject matter; a law of nature, natural phenomenon, or abstract idea. Within two months approximately 20 Amicus briefs were filed.[118]

2. The Substantive Issues

The Solicitor General also discussed the substantive law regarding the above exceptions to patentability under 35 U.S.C.

But because of *petitioner's* failure to rely on *Flook*'s inventiveness requirement below (or to raise any objection to patentability under Section 101), *respondents* had no incentive to argue in favor of a limiting construction of the patent, and the lower courts had no occasion to determine whether the patent could or should be read narrowly in light of that consideration. That failure to develop the contours of the claim in the context of the natural phenomenon issue is significant. As *Flook* explained and the dissent in *Diehr* repeatedly observed, the critical starting point in determining the validity of a claim for purposes of the natural phenomenon doctrine "is an understanding of what the inventor claims to have discovered." *Diehr*, 450 U.S. at 205 (Stevens, J., dissenting); accord *id.* at 193-194; *Flook*, 437 U.S. at 593 (noting that it is necessary "to determine what type of discovery is sought to be patented.").

115. *See id.* at 16-17.

116. *See id.* at 14.

Since this Court decided *Diehr* almost 25 years ago, PTO has generally followed the Federal Circuit's understanding that *Diehr* substantially limited *Flook*, and has issued numerous patents based on that understanding – including patents on medical diagnostic methods, other types of diagnostic and testing procedures, and computer-related processes. A decision overturning PTO's approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries.

117. *See id.* at 19.

118. *See* Docket for 04-607, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), http://www.supremecourtus.gov/docket/04-607.htm [hereinafter Court Docket].

§ 101.[119] The main Supreme Court decisions that were discussed in the Solicitor's Brief, as well as the amicus briefs, included *Diamond v. Diehr, Diamond v. Chakrabarty, Parker v. Flook, Gottshalk v. Benson,* and *Funk Bros. v. Kalo Inoculant.* These decisions refined the scope of what is eligible for patent protection under 35 U.S.C. § 101 and what may be unpatentable as one of the above exceptions.

The Solicitor General stated that the scope of patentable subject matter is usually broad,[120] but that the issue in this case was as follows:

> Claim 13 appears to *involve* such a natural phenomenon, because it asserts and relies on the existence of a naturally occurring correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate. The asserted natural relationship between elevated total homocysteine and deficiencies in the B vitamins appears to be an unpatentable "principle in natural philosophy or physical science," *Morse*, 56 U.S. (15 How.) at 116, just as the relationship between energy, mass, and the speed of light discovered by Einstein ($E=mc^2$), and the relationship between force of attraction, mass, and distance discovered by Newton (the law of gravity), are unpatentable natural phenomena. *See Chakrabarty*, 447 U.S. at 309. To the extent that the relationship is no more than an observable, naturally occurring fact of human physiology, it is also analogous to observations of the properties of bacterial strains and metals, which this Court has held to be unpatentable. *See Funk*, 333 U.S. at 130.[121]

Various amicus briefs concurred that claim 13 was not unpatentable because it involved a law of nature or natural phenomenon, since patents rely on laws of nature to some degree.[122] The tests for statutory subject matter in the Supreme Court decisions show that the application of a law of nature is only the beginning of the inquiry.[123] There are guidelines as to whether the application of a

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119. *See generally* Solicitor General Brief II, *supra* note 109, at 17-27.

120. *See* Solicitor General Brief I, *supra* note 97, at 5.

121. *See id.* at 6-7.

122. *See* Diamond v. Diehr, 450 U.S. 175, 189 n.12 (1981); *see also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 172 (1948); Solicitor General Brief I, *supra* note 97, at 6-7.

123. *See Diehr*, 450 U.S. at 187. "It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."

law of nature is patentable.[124] For example, the Solicitor General's brief identified two critical factors that should be addressed once one of the exceptions to statutory subject matter (like a law of nature) is implicated in a process claim. The Solicitor General asked: 1) did the claimed process transform an article into a different state or thing, and 2) did the claim cover all substantial uses of the method?[125] The Solicitor General suggested that if the answer to the first question was "no", or if the answer to the second question was "yes," then the claim was unpatentable under 35 U.S.C. § 101.

The Solicitor General also suggested that another question needed to be answered: namely, whether the law of nature was associated with the inventive concept of the claim.[126] The Solicitor General stated that it was unclear whether the Supreme Court had overruled their decision in *Parker v. Flook,* with their holding in *Diamond v Diehr.*[127] *Diehr* quoted *Flook* as stating that "the discovery of [a natural] phenomenon cannot support a patent unless there is some other *inventive* concept in its application."[128] In addition, *Diehr* noted that *Flook* was merely trying to patent a mathematical formula, whereas *Diehr* was seeking to patent the application of a mathematical formula in a method for curing rubber.[129] *Flook* was further distinguished in *Diehr* because their claim lacked sufficient

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124. *See id.* at 213 n.36. Even when a patent purports to apply a phenomenon of nature as part of a patentable process, the inquiry is not over:

> 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. [*Flook,*] 437 U.S. at 593.

Thus, it is necessary "to determine what type of discovery is sought to be patented." *Diehr,* 450 U.S. at 213 n.36.

125. *See* Solicitor General Brief I, *supra* note 97, at 10 (citing Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972)).

126. *See id.* at 11.

> This Court explained that 'once th[e] algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.' [*Flook,* 437 U.S.] at 594. Instead, the patent claim was merely 'comparable to a claim that the formula $2\pi r^2$ can be usefully applied in determining the circumference of a wheel.' [*Flook,* 437 U.S.] at 595.

Under *Flook,* therefore, an applicant could not claim patentable subject matter merely by setting forth a method that transformed matter and that did not claim all substantial practical applications of a natural phenomenon. Instead, the claim, considered as a whole, also had to contain some inventive aspect other than the natural phenomenon itself.

127. *Id.* at 17.

128. *See* Parker v. Flook, 437 U.S. 584, 594 (1978) (emphasis added).

129. *See Diehr,* 450 U.S. at 192-93.

details for use outside the mathematical formula.[130] The *Diehr* Court explained that natural phenomenon are not patentable in isolation and that the claim as a whole must be considered.[131] As a result, the Solicitor General suggested that it was unclear if the *Flook* test was still valid, or whether the *Diehr* test for the claim "as a whole" had substantially limited *Flook*.[132] That question would affect the substantive outcome in this appeal and they suggested that it needed to be addressed.[133]

After the Supreme Court granted certiorari, the government discussed several other issues in its December 23, 2005 brief. For example, it addressed the invalidity issues of indefiniteness enablement, written description, and anticipation.[134] It concluded that claim 13 satisfied all of the above requirements under 35 U.S.C. § 112.[135] However, it stated that the claim could be anticipated based on the treatment given by the courts below.[136]

The government also commented on the statutory subject matter questions that were raised in their earlier brief, i.e. transformation and preemption.[137] The Solicitor General stated: "Claim 13 appears to satisfy that test because the various methods of assaying for total homocysteine that are described in the record entail significant physical or chemical alteration of a sample of blood or other bodily fluid."[138]

The government went into some depth on the issue of whether claim 13 covered all substantial applications of the law of nature.[139] As to the specific facts presented in *LabCorp*, the Solicitor General stated that the jury's findings and the judge's comments suggested that the claim covered all substantial applications.[140] Nevertheless, the

130. Amicus Curiae Brief of American Intellectual Property Law Association in Support of Respondent at 11-12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303907 (hereinafter AIPLA Brief).

131. *Id.* at 12. ("The *Diehr* Court explained that although laws of nature, natural phenomena, and abstract ideas are not patentable in isolation, if the claim as a whole recites an application of a mathematical formula to a new and useful process, section 101 is satisfied.")

132. *See* Solicitor General Brief I, *supra* note 97, at 17; Solicitor General Brief II, *supra* note 109, at 21 n.4.

133. *See* Solicitor General Brief II, *supra* note 109, at 21 n.4.

134. *See id.* at 7-14, 28-30.

135. *See id.* at 7-14.

136. *See id.* at 28-30.

137. *Id.* at 17-29.

138. *Id.* at 21 n.4.

139. *Id.* at 22-29.

140. *Id.* at 22-23.

Solicitor General asserted that the case was not positioned for review as the issue had not been argued at the District Court or Federal Circuit.[141] However, the Solicitor General hypothesized that there were some potential non-infringing applications, such as testing something other than blood (tissue) and correlating without measuring.[142] If so, then the claim would not cover all substantial applications.

The discussion concerning all substantial uses was integral to the anticipation discussion. For example, if the claim covered all homocysteine assays as enjoined by the judge, then it covered any assays that were previously developed.[143] As with the section 101 issue, the Solicitor General felt that the anticipation issue was not "fairly included."[144]

Other amicus briefs supporting Metabolite generally focused on the Supreme Court decisions, which were expansive as to what constituted patentable subject matter. For example, *Diehr* was quoted as saying that the courts should not read limitations into patent laws that the legislature has not expressed,[145] along with *Diamond v. Chakrabarty* which suggests a broader reading of section 101 by stating that "anything under the sun that is made by man" would be patentable.[146] Supporting non-Supreme Court decisions include *In re Allappat* and *State Street Bank*, as they followed the *Diehr* rationale.[147]

> The district court instructed the jury that it should find petitioner liable for contributory infringement if, among other things, the total homocysteine assays performed by petitioner were not "capable of substantial noninfringing use." By finding petitioner liable for contributory infringement, the jury necessarily concluded that no substantial non-infringing uses of the total homocysteine assays had been proven on the trial record.

(citation omitted). The Federal Circuit affirmed the District Court's injunction to any and all homocysteine assays which would cover all substantial uses of the test. *Id.* at 24.

141. *Id.* at 22-24.

142. *Id.* at 25.

143. *Id.* at 29.

144. *Id.* at 6-7.

145. *See* Diamond v. Diehr, 450 U.S. 173, 182 (1981).

146. *See* AIPLA Brief, *supra* note 130, at 9; *see also* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

147. *In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994) (en banc); State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998).

The briefs in support of LabCorp generally focused on the requirement for transforming an article or thing from *Benson*.[148] They also relied on the public policy concerns regarding the breadth of patents and their power to exclude.[149] Some briefs discussed prior art related issues which are typically irrelevant to the issue of patentable subject matter under section 101.[150] One brief analogized the exceptions to section 101 in terms of the copyright merger doctrine by stating that when the idea or fact and expression are inseparable, copying the expression will not be barred.[151] Applying this logic to patentability, if the claim encompassed substantially all of the uses for the method, then the claim was unpatentable.[152]

3. Policy Issues from the Amicus Briefs

The amicus briefs were approximately evenly split in supporting both parties, and several supported neither party.[153] The amici included the Intellectual Property Owners Association, People's Medical Society, United States Government, American Clinical Laboratory Association, Financial Services Industry, Patients Not Patents, Inc., International Business Machines Corporation, Association of the Bar of the City of New York, American Express Company, Computer & Communications Industry Association, Affymetrix, Inc. and Professor John H. Barton, American Medical Association, AARP, Public Patent Foundation, Franklin Pierce Law Center, Boston Patent Law Association, Perlegen Sciences, Inc. and Mohr, Davidow Ventures, and the Federal Circuit Bar Association.[154]

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148. *See* Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 18, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3543098 (hereinafter American Clinical Lab. Brief).

149. *See* Brief for Amici Curiae Affymetrix., Inc. and Professor John H. Barton in Support of Petitioner at 14-15, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3597814 (hereinafter Affymetrix Brief).

150. Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 17, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3561169 [hereinafter American Heart Ass'n Brief]; *see also* Brief of Amicus Curiae People's Medical Society in Support of Petitioner at 19-21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3597702 [hereinafter People's Med. Soc. Brief].

151. Brief of the Public Patent Foundation as Amicus Curiae in Support of Petitioner at 15-16, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3597813 [hereinafter Public Patent Found. Brief].

152. *Id.*

153. *See* Court Docket, *supra* note 118.

154. *Id.*

As stated by Justice Breyer, the Court can obtain information on the facts and law from the parties' briefs, but the amicus briefs are generally most helpful on issues of public policy and how the cases would affect the groups represented by the authors.[155] Indeed, the amicus briefs raised interesting policy arguments on both sides of the debate. For example, one side was concerned about the loss of access to diagnostic tests, the affects on health care and costs for these services, while the other side discussed policies for encouraging innovation and the economic consequences which accompany the loss of patent protection for inventor's discoveries.

One main policy argument asserted that critical health care tests will become unavailable if patented because of the preclusive effect of patents.[156] Restricted access for diagnostic tests for the BRCA gene was given as an example.[157] One brief discussed privatization of correlations between genes and their functions.[158] They stated that obtaining a patent on the correlation between a genetic sequence and its function would put the ability to control research and scientific investigation into private hands.[159] They mentioned that this problem becomes more significant as research goes beyond the one gene, one disease model and into areas that require many multiples of genes to uncover the underlying basis for disease.[160] This is a very real concern as researchers are using tools that contain all known human gene sequences in one test.[161] If one or more patentees can control a particular gene or its correlation, then they may foreclose the larger experiments and the discovery of further correlations with other genes or diseases.

Another brief stated that physicians would no longer be able to prescribe diagnostic tests for homocysteine, and other briefs extended

155. *See* Associate Justice Stephen G. Breyer, *Genetic Advances and Legal Institutions,* 28 J.L. MED. & ETHICS 23, 24-25 (2000).

156. American Clinical Lab. Brief, *supra* note 148, at 8-9.

157. Affymetrix Brief, *supra* note 149, at 18.

158. *Id.* at 16-20. Generally, gene patents have been determined to have utility, but some have questioned their ability to pass the "originality" standard. *See* Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261 (2005).

159. Affymetrix Brief, *supra* note 149, at 16-17.

160. *Id.* at 18.

161. Affymetrix sells nucleic acid probe arrays that have this capability. *See* Affymetrix, Products: Gene Chip Arrays, http://www.affymetrix.com/products/arrays/index.affx (last visited Oct. 23, 2007).

this idea to all current diagnostic tests.[162] These briefs suggest that there would be a negative impact on the physician/patient relationship if claim 13 was upheld.[163] Other amici suggested that claim 13 would deter physicians from ordering diagnostic tests or obtaining genotype information.[164]

The specific fact situation presented in *LabCorp* may not be representative of every dispute in similar situations, but it did not appear that the litigation would have affected access to homocysteine tests because the dispute was simply over a royalty owed under a preexisting agreement. Therefore, no physician would have to forego a test for total homocysteine. With respect to the general issue of patient access to tests, one brief countered that patents with claims similar to claim 13 have been around for some time and there was no evidence presented that physicians were ever sued under the '658 patent. Furthermore, physicians would not be sued under currently typical diagnostic test patents.[165] Health care, like many industries, is practiced in an environment where patented inventions are used constantly and they do not limit access to care.[166] In fact, one brief

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162. *See* Brief for the American Medical Association, et al., as Amici Curiae in Support of Petitioner at 25, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3597812 [hereinafter AMA Brief].

163. *See* also American Heart Ass'n Brief, *supra* note 150, at 24-26; People's Med. Soc. Brief, *supra* note 150, at 23.

164. *See* Affymetrix Brief, *supra* note 149, at 16.

165. Brief for Amici Curiae Perlegen Sciences, Inc. et al. in Support of Respondents at 20-21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303908 [hereinafter Perlegen Brief]; *see also* Brief for Respondents at 48, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303905 [hereinafter Respondents' Brief].

> Petitioner is a for-profit company that is seeking to maximize its revenue by avoiding the royalties due respondents under the licensing agreement that petitioner previously entered into. There is not a shred of evidence in the record that petitioner's payment of royalties to respondents, or the ultimate cost of the homocysteine assays performed by petitioner, have ever affected a single doctor's treatment decision. There is absolutely no evidence that, if the judgment below were affirmed (or the writ dismissed), any patient's care, or the cost of that care, would change in any way.

Respondents' Brief at 48.

166. *See* Respondents' Brief, *supra* note 165, at 48-49.

> Patented inventions are common in the field of medicine. In addition to diagnostic methods, a physician may employ diagnostic machinery (such as an MRI machine), medical devices (such as implants or prosthetics), and of course a wide range of pharmaceuticals, all of which may be covered by one or more patents. For this reason, AARP's assertion (Br. 9) that claim 13 "would prohibit physicians from practicing good medicine without a patent license" proves far too much. "Good medicine" may in fact require physicians to practice patented inventions on a daily basis – by engaging in patented diagnostic methods, by

asserted that patents do not negatively affect testing as the diagnostic market is accelerating, not decelerating.[167] These factors suggest that diagnostic tests should be more available in the future, not less available as asserted. Access to diagnostic tests may be less related to patents than to health insurance related reimbursement issues.

It was also asserted that patents would increase the cost of health care by requiring that a health care provider postpone a diagnosis to do a patent search.[168] However, the briefs did not show any evidence that physicians have ever performed patent searches or have impeded their patient relationship, even though diagnostic patent claims have been around for many years.[169] Also, it seems evident that even if claim 13 were unpatentable, it would not change a researcher/physician's duty to perform a search for otherwise relevant patents. Therefore, it seems unlikely that the disposition of claim 13 would affect this hypothetical situation either way.

It was also asserted that the public would be excluded from the use of any newly discovered natural law, and that if the decision is affirmed, "the availability of new and improved tests would be entirely at the mercy of the person who first discovered the natural correlation."[170] As stated above, it is clear that an applicant can obtain a patent applying a correlation of a natural phenomenon.[171] Indeed, this is the basis for many patents. In the medical field, it is a correlation between disease and drug that is important for pharmaceutical companies and the correlation between marker and disease for diagnostic companies. It is simply a question of

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> using patented devices, or by prescribing patented pharmaceuticals. Although the patent regime may increase (or decrease) the cost of patient care, Congress has made the policy judgment that the benefits of increased innovation provided by the patent system justify any distortions that patents might introduce into the healthcare delivery system.

167. *See* Perlegen Brief, *supra* note 165, at 21.

168. *See* People's Med. Soc. Brief, *supra* note 150, at 22.

169. *See generally* Respondents' Brief, *supra* note 165, at 48-49.

170. *See* American Clinical Lab. Brief, *supra* note 148, at 9.

171. *See* Diamond v. Diehr, 450 U.S. 175 (1981); Perlegen Brief, *supra* note 165, at 11; Solicitor General Brief I, *supra* note 97, at 14. *See also* Respondents' Brief, *supra* note 165, at 46:

> And pharmaceutical companies could not patent methods of treating conditions such as depression, Alzheimer's, or heart disease with drugs, since they have merely discovered that certain chemicals interact with the human body in ways directed by chemistry and patented practical applications of such discovered interactions. *Cf Diehr*, 450 U.S. at 189 n.12 ("To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.").

formulating the claims in such a way so as not to run afoul of the exceptions to patentability that have been identified by the above cases, most notably, the transformation requirement and the preemption issue. Even if claim 13 were invalid in its current form, the essence of the correlation may be claimed in another form. Consequently, claims of some relevant breadth could still exist. However, drafting a patentable claim will require a compromise between compliance with section 101 and claim scope. The Solicitor General's December 23, 2005 brief asserts that the narrower a claim is drafted, the more likely it will not cover all substantial uses of a natural law.[172] However, the usefulness of the claim may then be negated. Also, claiming a transformation step will limit claim scope, as a particular transformation may require a limitation that relates to a specific embodiment of an invention. It may be true that narrowing a claim will lessen the issues under section 101, but the consequence is that its value is diminished.

First Amendment issues were also raised by some of the amicus briefs,[173] asserting that claims similar to claim 13 would chill free speech, restrict the dissemination of medical info and abridge the right to think because actions may be regarded as potential patent infringement.[174] Regarding the conflict between the First Amendment and infringement, 35 U.S.C. § 271 defines the elements of patent infringement: publication and dissemination of information are not infringement by themselves. If published information is relevant to a claimed method, then the patentee still needs to show how the defendant's conduct satisfied the other limits of the claims.[175]

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172. Solicitor General Brief II, *supra* note 109, at 28.

173. People's Med. Soc. Brief, *supra* note 150, at 17-19; Public Patent Found. Brief, *supra* note 151, at 17; Affymetrix Brief, *supra* note 149, at 26.

174. People's Med. Soc. Brief, *supra* note 150, at 19:

> The Federal Circuit held that LabCorp indirectly infringed claim 13 of the '658 patent by publishing basic scientific information. Such a holding chills the exercise of freedom of speech. This result denies physicians hoping to treat ill patients access to basic scientific information and restricts the ability of other scientists to undertake further research regarding the information and publish the results of that research.

(citations omitted).

175. *See supra* note 97 for a discussion of infringement by multiple parties. *See also* Respondents' Brief, *supra* note 165, at 38:

> In any event, claim 13 is only infringed when the assaying and correlating steps are *both* performed, sequentially, for the purpose of diagnosing vitamin deficiencies. The act of assaying body fluids for total homocysteine for reasons other than diagnosing vitamin deficiencies would not infringe. Nor would the act

Publication alone would not fit within the assaying limitation of claim 13 and therefore there would be no danger in publication and dissemination of scientifically relevant information.[176] It should be remembered that *LabCorp* provided articles that commercially benefited their assaying business. Publication would not constitute infringement of the typical diagnostic claim, which generally requires an active step to obtain a sample for analysis, or some other action not generally associated with publication. Consequently, claims of this type should not abridge First Amendment rights by mere publication.

It was also argued that *LabCorp* was simply publishing old information about a natural phenomenon and that they should not be able to prevent this activity.[177] This assertion confuses the issues and attempts to raise a prior art argument in the discussion regarding statutory subject matter.[178] As mentioned above, it is not relevant in the context of section 101. Additionally, the prior art and other validity issues were not at issue at the Supreme Court and were resolved in favor of the patentees by the Federal Circuit.[179] Also, the information in the briefs suggested that these inventors, who were medical school professors, were the first to describe the method to detect homocysteine and the correlation between homocysteine and the vitamin deficiencies.[180] Neither discovery was known until the inventors published their findings and then persuaded their colleagues

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of correlating alone, or what petitioner calls "thinking about" the relationship between total homocysteine and vitamin deficiencies.

176. *See supra* note 97 for split infringement discussion. *See also* Respondents' Brief, *supra* note 165, at 38 n.18:

> *[S]ee MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935 (2005) ('The classic case of direct evidence of unlawful purpose occurs when one induces commission of infringement by another, or entices or persuades another to infringe, as by advertising') (internal quotation and citation omitted). Whether other persons or entities infringe the '658 patent is separate question on which no evidence was presented below.

177. People's Med. Soc. Brief, *supra* note 150, at 19-20. *See also* Public Patent Found., *supra* note 151, at 17; *see also* Affymetrix Brief, *supra* note 149, at 25-26.

178. *See* Amicus Curiae Brief of the Ass'n of the Bar of the City of N.Y. in Support of Neither Party at 8-9, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607) (showing that a section analysis does not incorporate issues of other sections such as 102, 103 or 112).

179. Solicitor General Brief II, *supra* note 109, at 28-30. *But see generally* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366-68 (Fed. Cir. 2004) (where claims could be anticipated based on the jury findings and the judge's injunction).

180. Respondents' Brief, *supra* note 165, at 3-4 ("The Inventors were the first to study the relationship between total homocysteine and deficiencies of cobalamin and folate. In fact, they were the first to even measure total homocysteine in patients with known cobalamin or folate deficiencies.").

of the usefulness of the assay and correlation.[181] Therefore, the inference that they were not the first inventors was misplaced.

Policy arguments supporting patentability for claim 13 under section 101 asserted that, without a broad reading of patentable subject matter, there would no longer be incentives for research leading to future invention and that innovation would stagnate if there was less protection for diagnostic inventions.[182] In other words, if there is no prospective financial benefit or if there is lack of commercial protection from larger companies, then smaller companies will not expend the time and money to invent or bring health care inventions to market in the first place. Diagnostic tests will trend towards those methods that are older and proven since there will be less incentive for developing/discovering new tests. Large diagnostic companies would be more likely to use existing tests without the need to advance. Companies will not perform research directed at finding a workaround as there would be no need to do so and no reward once they found it. Also, if there is no seed money for small diagnostic or biotechnology companies, funding will move to other industries which are entitled to patent coverage and the United States position in biotech will erode. One example, illustrating how policy changes shift investment in research, is the movement out of the country due to the lack of funding for stem cell research in the United States.[183]

However, it is generally recognized that patent protection for new ideas fosters innovation.[184] One brief specifically showed how a non-patent form of exclusivity can increase the incentives to address the needs of public health.[185] The example is the Orphan Drug Act of 1983, which sets up a mechanism to provide exclusive rights to a party who develops a disease treatment for diseases that do not have a broad base of affected individuals, thereby making health care more available to the public.[186] This exclusivity benefits consumers by bringing drugs to the people that would otherwise not have received them and can be likened to the exclusivity provided by patents.

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181. *See id.* at 4-5.

182. *See* Brief Amicus Curiae Franklin Pierce Law Center in Support of Respondents at 17-19 & n.10, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607) [hereinafter Franklin Pierce Brief]; Perlegen Brief, *supra* note 165, at 18-19.

183. *See* Matthew Herper & Robert Langreth, *Anti-ban Billionaires*, FORBES MAG., Sept. 4, 2006, http://www.forbes.com/business/forbes/2006/0904/124.html.

184. *See generally* Franklin Pierce Brief, *supra* note 182, at 13-19.

185. *See id.* at 17-18.

186. *See id.* at 17-19.

Accordingly, granting patents would similarly serve the policy of encouraging innovation as well as providing greater access to health care and diagnostic tests.

Another important policy reason was the negative effect on many other patent claims if claim 13 was held unpatentable under 35 U.S.C. § 101.[187] The Solicitor General stated: "[a] decision overturning the PTO's approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries."[188] A simple search of U.S. patents on the USPTO database shows that there are many patents that use "correlating" in the claim. One brief explained: "[v]irtually every patent claim concerning a diagnostic method is based, explicitly or implicitly, on a medical condition. Thus, the repercussions for biotechnology, particularly diagnostics, if the decision below were reversed would be staggering."[189] They list fundamental patents to Bayer on PSA, Stanford for HIV/AIDS, University of California for HER-2/neu, and Johns Hopkins for cancer, as examples.[190] Additionally, depending on its scope, a decision adverse to *Metabolite* could overturn twenty-five years or more of case law both at the Federal Circuit and the Supreme Court.[191] As the Solicitor General stated, overturning this precedent would have a tremendous effect on companies of all sizes. Business plans would be tossed out the window with tremendous upheaval in expected returns. Shareholders and other investors would lose money or be wary of investing in ventures that were dependant on patented products, assays, or other methods. Consequently, several amicus briefs stated that it was good policy to either not decide the issue in this case because it was not fully vetted, decide it in a narrow way, or hold in favor of patentability.[192]

Other briefs stated that it was hard to apply the law of nature exception and that Congress wants a broad definition of what is patentable.[193] Justice Frankfurter's concurrence in *Funk Bros.*

187. *See* Perlegen Brief, *supra* note 165, at 11. *See generally* Solicitor General Brief II, *supra* note 109, at 14.

188. Solicitor General Brief I, *supra* note 97, at 14.

189. Perlegen Brief, *supra* note 165, at 11.

190. *See id.* at 12-13.

191. *See* Respondents' Brief, *supra* note 165, at 44; Solicitor General Brief I, *supra* note 97, at 14, 15 n.*.

192. *See, e.g.*, Solicitor General Brief I, *supra* note 97, at 15.

193. *See, e.g.*, Franklin Pierce Brief, *supra* note 182, at 26-29.

supports this view.[194] It could be argued that the system needs to have a broad view of utility due to the emergence of new technologies which may not fit neatly into existing categories.[195] Otherwise, a policy is set to selectively discriminate against particular technologies by favoring one industry over another. In the area of statutory subject matter, the industries include biotechnology, diagnostics, and emerging markets such as signal processing and business methods.

4. The Decision

The hearing was March 21, 2006 and the case was dismissed as improvidently granted on June 22, 2006.[196] A dissent was written by Justice Breyer, and joined by Justices Stevens and Souter.[197]

5. The Dissent

Justice Breyer felt that the Court should exercise their discretion to decide the issues because they already had enough information to do so.[198] He stated that there was no practical reason for not hearing the case, that neither the factual record nor the briefing was inadequate, no party claimed prejudice, and there was no unfair gamesmanship.[199] He stated that even though lower court consideration is helpful, he believed that it was more important to clarify the law in this area sooner than later.[200]

With respect to the substantive issues and policy considerations, Justice Breyer stated that "the process described in claim 13 is *not* a process for transforming blood or any other matter."[201] His comments focus on the purpose of the physical transformation by requiring that

194. *See generally* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134-35 (1948) (Frankfurter, J., concurring).

195. *See generally* Eileen M. Kane, *Patent Ineligibility: Maintaining A Scientific Public Domain,* 80 ST. JOHN'S L. REV. 519, 520-23 (2006).

196. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006); Supreme Court of the U.S., Hearing List (Mar. 20, 2006), *available at* http://www.supremecourtus.gov/oral_arguments/hearinglists/hearinglist_mar06.pdf.

197. *Lab. Corp.*, 126 S. Ct. at 2921 (Breyer, J., dissenting).

198. *Id.* at 2922.

> In my view, we should not dismiss the writ. The question presented is not unusually difficult. We have the authority to decide it. We said that we would do so. The parties and *amici* have fully briefed the question. And those who engage in medical research, who practice medicine, and who as patients depend upon proper health care, might well benefit from this Court's authoritative answer.

199. *See id.* at 2926.

200. *See id.*

201. *Id.* at 2927.

it be related to the novel aspect of the claim.[202] He also criticized the assaying step by stating that it can employ any test at all, suggesting that there should be something inventive in this part of the claim.[203] The Solicitor General did not make the same distinction and would accept that there was a physical transformation in claim 13.[204] It is irrelevant that the step is not patented unless Justice Breyer believed that *Flook* is more controlling than *Diehr*.

Justice Breyer also addressed the "useful, concrete and tangible result" test set out in *State Street Bank* and said that the Supreme Court had never authorized such a test "and, if taken literally . . . would cover instances where this Court has held the contrary." [205] This statement also signals that the Supreme Court is interested in cutting back on the breadth of statutory subject matter set out by the Federal Circuit. These comments are already being applied at the Board of Patent Appeals and Interferences, which questioned the above test in *Ex parte Glenner* as discussed later in this article. However, this test is still in use at the Federal Circuit.

The dissent concluded that the physical transformation step is irrelevant because claim 13 covers any test.[206] Justice Breyer claimed that the limitation preempts all substantial uses of the law of nature and therefore is inapplicable as a claim limitation.[207] Instead, he focused on the correlating limitation and concluded his analysis by saying that claim 13 simply described a natural process in the abstract language of a process and that it is just an instruction to read some numbers in light of medical knowledge.[208] One can always claim any process as a series of steps, but the question is what the steps embody.[209] Is it a natural phenomenon or not? These comments suggest that the dissent wants more actual, physical limits in claims, to make them narrower across the board.

Justice Breyer concluded with the public policy argument that uncertainty in this area threatens the medical profession and stated that a decision would reduce legal uncertainty.[210] He also echoed

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202. *See id.* at 2927-28.

203. *Id.*

204. Solicitor General Brief I, *supra* note 97, at 9-10; Solicitor General Brief II, *supra* note 109, at 21 n.4.

205. *Lab. Corp.*, 126 S.Ct. at 2928 (Breyer, J., dissenting).

206. *Id.* at 2927.

207. *See id.* at 2922-28.

208. *See id.* at 2928.

209. *Id.*

210. *See id.* at 2928-29.

concerns that physicians have to spend time searching and licensing patents, diverting them from practicing medicine which, in turn, drives up health care costs.[211] His last comments expressed an interest in having a debate between the generalists and the specialists over whether "the patent system, as currently administered and enforced, adequately reflects the 'careful balance' that 'the federal patent laws. . . embod[y]."[212] However, once the Supreme Court has spoken on an issue, that usually ends the discussion. Clearly, one can see that this Supreme Court is quite willing to reevaluate and challenge some longstanding intellectual property case law as they have shown in several decisions in the last few years.

It is possible that the full court would have found the claim unpatentable because of the policy arguments recited in the Breyer dissent. Recent Supreme Court opinions have favored policy concerns that have narrowed intellectual property protection.[213] Other policy arguments that could be persuasive relate to fostering public health; allowing public dissemination of important health information; promoting the physician/patient relationship; and lowering the costs of diagnostic tests. However, it is not clear that less protection for intellectual property will achieve those goals.

The Court could also hold that the *Flook* test is still alive and some element of novelty needs to be in the claim outside of the law of nature limitation. Application to these facts could mean that claim 13 was unpatentable as the assaying step was not new.

IV. DECISIONS ISSUED AFTER *LABCORP*

We will not know how the Supreme Court would have decided the utility issues in *LabCorp* or how they will decide these issues when they return to the Court. We do know that the justices are interested in resolving intellectual property issues generally and have expressed interest in this particular issue. The chances are good that the Court will address statutory subject matter soon. It is evident that a block of three justices would have decided that claim 13 was directed to nonstatutory subject matter.[214] Would any other two

211. *Id.* at 2928.

212. *Id.* at 2929 (citations omitted) (alteration in original).

213. *See, e.g.*, KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007).

214. *See generally Lab. Corp.*, 126 S. Ct. 2921 (Breyer, J., dissenting) (with whom Stevens, J., and Souter, J., joined). See also *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124 (2001), where Justices Breyer and Stevens dissented from the holding that plants could be subject of utility patents.

justices follow suit if the question was fully developed in the lower courts?

The following discussion is a survey of case law decided after *LabCorp* and may be helpful in understanding the impact and the social context for the Supreme Court decision yet to come. Several of the later decisions have issued from the Board of Appeals and Interferences of the U.S. Patent Office. [215] Two were decided at the Federal Circuit and one from a District Court infringement action.[216] The number of section 101 appeals has increased in the last year, in part because, like the Supreme Court, the Board and the Federal Circuit have been raising the utility issue *sua sponte*.[217] The claimed subject matter in the appeals has been largely in the computer algorithm and signals area and one commentator observed that the Board has justified their conservative view of utility under section 101 by referring to cases that have been overruled or disfavored.[218] In their decisions, the Board has discussed older Supreme Court and pre-*State Street Bank* precedent in distinguishing *State Street Bank,*[219] as well as similar decisions such as *Arrhythmia*, *ATT* and *In re Alappatt*.[220] The only recent District Court action relates to a patent claiming a schedule for immunizing mammals, and is therefore more similar to *LabCorp* than the Board and Federal Circuit cases.

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215. *Ex parte* Casazza, Appeal No. 2006-2228, 2006 WL 2794039 (B.P.A.I. Sept. 6, 2007) (signal); *Ex parte* Glenner, Appeal No. 2007-1089, 2007 WL 1874818 (B.P.A.I. June 28, 2007); *Ex parte* Gutta, Appeal No. 2006-2107, 2007 WL 1766997 (B.P.A.I. June 11, 2007); *Ex parte* Jakobsson, Appeal No. 2006-2107, 2007 WL 1371371 (B.P.A.I. Apr. 16, 2007); *Ex parte* Rising, Appeal No. 2007-0438, 2007 WL 1033504 (B.P.A.I. Mar. 20, 2007) (processing method); *Ex parte* Keohane, Appeal No. 2006-3121, 2007 WL 375026 (B.P.A.I. Jan. 31, 2007) (data processing); *Ex parte* Hartmann, Appeal No. 2006-1607, 2006 WL 2700810 (B.P.A.I. Sept. 13, 2006) (signal); *Ex parte* Bilski, Appeal No. 2002-2257, 2006 WL 4080055 (B.P.A.I. Mar. 8, 2006).

216. *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007); *In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007).

217. *See* Peter Zura, "Waiting for Nuijten" - 101 Rejections at the BPAI (part 2), Sept. 12, 2007, http://271patent.blogspot.com/2007/09/waiting-for-nuijten-101-rejections-at_12.html; Peter Zura, "Waiting for Nuijten" - 101 Rejections at the BPAI (part 1), Sept. 11, 2007, http://271patent.blogspot.com/2007/09/waiting-for-nuijten-101-rejections-at.html.

218. *See* Peter Zura, "Waiting for Nuijten" - 101 Rejections at the BPAI (part 1), Sept. 11, 2007, http://271patent.blogspot.com/2007/09/waiting-for-nuijten-101-rejections-at.html. (referring to *In re* Schrader, 22 F.3d 290 (Fed. Cir. 1994); *In re* Warmerdam, 33 F.3d 1354 (Fed. Cir. 1994); *In re* Abele, 684 F.2d 902 (C.C.P.A. 1982); *In re* Walter, 618 F.2d 758 (C.C.P.A. 1980); *In re* Freeman, 573 F.2d 1237 (C.C.P.A. 1978)).

219. State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998).

220. AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352 (Fed. Cir. 1999); *In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994); Arrhythmia Research Tech. Inc. v. Corazonix Corp., 958 F.2d 1053 (Fed. Cir. 1992).

A. Ex Parte Bilski[221]

Two other appeals arrived at the Federal Circuit prior to *Bilski*: *In re Comiskey* and *In re Nuijten.* However, the Board discussed its section 101 analysis more extensively in *Bilski,* which is still in the briefing stages at the Federal Circuit.[222]

The invention is claimed as a non-machine implemented business method: hedging risks associated with commodity price.[223] It is a business method patent without a physical device or physical transformation. The PTO rejected the claims solely under 35 U.S.C. § 101 as being directed to nonstatutory subject matter, stating that "the bounds of patentable subject matter are increasingly being tested" with non-computer implemented process claims.[224] The Board stated that non-machine implemented methods can be problematic as they are able to cover abstract ideas, which is a common theme for algorithm claims.[225] The Board applied many of the tests from prior

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221. *Ex parte* Bilski, Appeal No. 2002-2257, 2006 WL 4080055 (B.P.A.I. Mar. 8, 2006).

222. *See id.* at *2-4. The same section 101 issue was raised during the oral hearing by Chief Judge Michel in *In re* Comiskey, 499 F.3d 1365, 1371 (Fed. Cir. 2007), requiring supplemental briefing.

223. *See Bilski*, 2006 WL 4080055 at *1. This opinion was not designated for publication.

> The invention relates to a method practiced by a commodity provider for managing (*i.e.,* hedging) the consumption risks associated with a commodity sold at a fixed price. It is disclosed that energy consumers face two kinds of risk: price risk and consumption risk (specification, p. 1). The proliferation of price risk management tools over the last 5 years before the filing date allows easy management of price risk (specification, p. 2). However, consumption risk (*e.g.,* the need to use more or less energy than planned due to the weather) is said to be not currently managed in energy markets, which is the problem addressed by the invention (specification, p. 2).
>
> Claim 1 is reproduced below.
>
> 1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:
>
> (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> (b) identifying market participants for said commodity having a counter-risk position to said consumers; and
>
> (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

224. *Id.* at *3.

225. *See id.* at *2.

precedent and noted that the present claims did not have any of the common attributes that convey patentability under section 101.[226]

> The steps of claim 1: do not recite any specific way of implementing the steps; do not expressly or impliedly recite any physical transformation of physical subject matter, tangible or intangible, from one state into another; do not recite any electrical, chemical, or mechanical acts or results; do not directly or indirectly recite transforming data by a mathematical or non-mathematical algorithm; are not required to be performed on a machine, such as a computer, either as claimed or disclosed; could be performed entirely by human beings; and do not involve making or using a machine, manufacture, or composition of matter.[227]

Judge Barrett wrote the decision and pointed to *Ex parte Lundgren* as discussing the legal analysis of statutory subject matter and went through the stepwise analysis set out in the Interim Guidelines, the PTO test for patentability under section 101.[228] He focused on the definition of the word "process" and identified it as the most difficult category of section 101 to define because these claims do not recite structure and can therefore be more abstract.[229] One key feature for defining a process is whether the subject matter is physically transformed into tangible or intangible matter.[230] However, the transformation test is not without differing interpretations, as the dissent in *LabCorp* focused on the purpose of the transformation as relevant to patentability.[231] The "assaying" step in the *LabCorp* claim could be interpreted as requiring a transformation, but the focus of novelty was not that particular transformation.[232] However, the Board also stated that:

> Where the steps define a transformation of physical subject matter (tangible or intangible) to a different state or thing, as normally present in chemical, electrical, and mechanical cases, there is no question that the subject matter is statutory; e.g., "mixing" two

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226. *See id.*

227. *Id.*

228. *See id.* at *4; *Ex parte* Lundgren, 76 U.S.P.Q.2d 1385, 1393-94 (B.P.A.I. 2005) (precedential); USPTO, Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Nov. 22, 2005), http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf (hereinafter Interim Guidelines).

229. *Lundgren*, 76 U.S.P.Q.2d at 1399, 1409.

230. *Id.* at 1400.

231. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2927 (2006) (Breyer, J., dissenting) (emphasis added).

232. *See id.* at 2924.

> elements or compounds is clearly a statutory transformation that results in a chemical substance or mixture although no apparatus is claimed to perform the step and although the step could be performed manually.[233]

Even though the claim is not directed at a transformation, one could argue that transformations may occur. Language differences between words such as "assaying" and "mixing" may be important in biotechnology claims, as those words can be used frequently to add steps that convey the use of physical devices or physical transformations. These terms will still need to be analyzed as to their function within the claim. For example, *Bilski* cited *Lundgren* for the proposition that not all action may convey utility: "[i]ncidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are not enough to convert an 'abstract idea' into a statutory 'process'."[234] The analysis may inject some of the *Flook* test and require that the physical step be part of the inventive concept and not an insubstantial activity. Again, this is a similar concern to that discussed by Justice Breyer for the assaying step in claim 13.[235]

The Board discussed the three exclusions to patentability, *i.e.,* laws of nature, natural phenomenon, and abstract ideas.[236] They focused on the abstract idea exclusion and identified relevant issues for that analysis.[237] Transformation was one; another was whether the claim covered substantially all of the practical applications of a way the steps were performed (preemption).[238] The Board likened preemption to the analysis in *LabCorp* where the assaying step could be performed by any test at all.[239] The Judges also questioned the helpfulness of the "useful, concrete, and tangible result" test to determine statutory subject matter and thought that it was redundant with the existing plain language of the statute.[240]

Ultimately, the Board rejected the claims as nonstatutory subject matter by stating that the claim was not computer related, that it was not a process because it was an abstract idea, there was no

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233. *Ex parte* Bilski, Appeal No. 2002-2257, 2006 WL 4080055, at *11 (B.P.A.I. Mar. 8, 2007) (citing *Lundgren,* 76 U.S.P.Q.2d at 1417).

234. *Id.* at *8 (citing *Lundgren*, 76 U.S.P.Q.2d at 1401).

235. *See generally Lab. Corp.*, 126 S. Ct. at 2926-28 (Breyer, J., dissenting).

236. *Bilski,* 2006 WL 4080055, at *7.

237. *See id.* at *8.

238. *See id.*

239. *See id.*

240. *See id.* at *10.

transformation, and the claim would cover substantially all practical uses of the idea.[241] Judge Barrett commented on what he thought was the important factor by saying "the transformation of physical subject matter test is a more objective way to perform the [section] 101 analysis for non-machine-implemented method claims."[242]

This decision is interesting as it provides one of the most extensive discussions of the problems faced by the PTO in struggling with the issue. Judge Barrett wrote the decision and he has been involved in many Board decisions on this matter.[243] He was clearly interested in guidance from the Federal Circuit and posed fourteen questions that he would like to see answered.[244] For example, among other questions, he asked: does a process always require transformation; is it sufficient that energy be transformed; will the use of a general purpose machine always make a claim statutory, even when the machine is old; when will a physical step convert the claim into statutory subject matter; is *State Street Bank* limited to transformation of data by a machine; and what is the definition of "useful, concrete, and tangible"?[245] The issue to be decided on appeal will relate to the requirement for a physical transformation or physical device in the claims versus the application of the "useful, concrete, and tangible result" test without a machine.[246] Since this test was questioned by Justice Breyer in his *LabCorp* dissent, it will be useful to see how the Federal Circuit addresses this issue again after *In re Nuijten*. Clarification of the questions will be important for future guidance.

B. In re Nuijten[247]

In re Nuijten was decided by the Federal Circuit and was one of two recent opinions to discuss section 101. Nuijten's application contained claims to a process for encoding a signal (1-10), an arrangement for embedding supplemental data in a signal using an encoding means (11-13), a signal (14, 22-24), and a storage medium having a signal with embedded supplementary data (15). [248] All claims but number 14 were allowed, which was the subject of the

241. *See id.* at *11-12.
242. *Id.* at *30.
243. *See id.* at *1.
244. *See id.* at *13-15.
245. *See id.*
246. *See id.*
247. *In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007).
248. *See id.* at 1351.

appeal. [249] The signal was an audio or video watermark that was embedded to protect against unauthorized copying.[250]

The examiner rejected the claims as an abstract idea with no physical embodiment.[251] The applicants rebutted that statement and replied that "a signal is not abstract, but '[s]aid signal comprises energy, is detectable, and measurable [and] is as physical and tangible as a table or a baseball' and is not naturally occurring."[252]The Board held that the claims were nonstatutory because they represented an abstract idea which was not in one of the four statutory categories.[253]

The Court of Appeals for the Federal Circuit reviewed the section 101 issue de novo in *In re Nuijten*.[254] The holding by the majority framed the issue as an inquiry into whether the appealed claims fit into one of the four categories of statutory subject matter, namely process, machine, manufacture, or composition of matter.[255]

The Court construed the claims first, which can often determine the end result. The construction focused on the physical nature of the signal.[256] The Court determined that the signal was itself physical, but it needed some other physical structure for practical use.[257] The Judges stated: "[h]owever, while the claims are limited so as to require some physical carrier of information, they do not in any way specify what carrier element is to be used. The only limitations in claim 14 address the signal's informational content."[258] The Court

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249. *See id.*

250. *See id.* at 1348-49.

251. *See Ex parte* Nuijten, Appeal No. 2003-0853, 2006 WL 3939192, at *1-2 (B.P.A.I. Jan. 24, 2006).

252. *See id.* at *2 (alterations in original).

253. *See id.* at *3.

254. *In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007).

255. *See id.* at 1353.

256. The Court stated:

> The claim construction dispute between Nuijten and the PTO turns on a somewhat esoteric and metaphysical point, namely: are the claims at issue limited to covering only physical instances of signals, or do they also cover intangible, immaterial strings of abstract numbers? The PTO suggests that "claim 14 can be read to claim a signal that is merely data" – that is, merely numerical information without any physical embodiment. Nuijten disagrees, arguing that "a signal must have sufficient physical substance to be discerned and recognized by a recipient." That is, a signal can be sensed and received by some physical apparatus, if not directly by a person.

Id. at 1353.

257. *See id.* at 1353.

258. *Id.*

stated that since there was no explicit structure for the signal, any tangible means would be covered by the claim.[259]

Nuijten and the PTO had agreed that the signal was physical, but transitory in nature.[260] The Court determined that transitory physical signals were not statutory subject matter because they did not fit within one of the four statutory subject classes: process, composition, machine or article of manufacture.[261] For example, the signal of claim 14 did not require an action, so it was not a process; it was not a concrete thing having parts, so it was not a machine; and it was not a chemical union, a mechanical mixture, gas, fluid, powder or solid, so it was not a composition of matter.[262] However, the Court had the most difficulty determining that a signal was not an article of manufacture.[263] A signal is manufactured by man, but being made by man is not the only criteria for statutory subject matter.[264] The definitions the Court found for "manufacture" related to tangible commodities and concluded that even though a signal was man-made, physical and causes tangible effects, it was fleeting and devoid of permanence.[265] So, they held that the signals standing alone were not "manufacture(s)" as contemplated by section 101.[266]

The dissent agreed with the majority that the signal was physical, but, unlike the majority, found that it was statutory subject matter.[267] Judge Linn stated that the policy favoring what was statutory should be read broadly so as to accommodate new technologies.[268] He refuted the idea that a signal was not patentable because it was transitory or lacked permanence, by referring to patents that claimed chemical intermediaries. He also referred to *Application of Hruby*,[269] where a patent was awarded for a transient water fountain display. Judge Linn also referred to the test in *Alappat*, which suggests that an

259. *See id.*

260. *Id.*

261. *See id.* at 1353-54. The court first distinguished its comments in *State Street Bank* which suggested that an invention need not be placed into one of the above classes. It clarified that a claimed invention must fall into a class, only that it was not critical that the specific class need to be determined. It stated that the question here was whether the claims fell into any class, not just which one.

262. *Id.* at 1355-57.

263. *See id.* at 1356.

264. *See id.*

265. *Id.* at 1356.

266. *Id.* at 1357.

267. *See id.* at 1358 (Linn, J., concurring-in-part and dissenting-in-part).

268. *See id.*

269. *In re* Hruby, 373 F.2d 997 (C.C.P.A. 1967).

invention is patentable if it produces a useful, concrete, and tangible result, and he noted that it does not require that the claimed subject matter be a tangible thing.[270]

Judge Linn concluded with the observation that claims should be given wide scope in the section 101 analysis.[271] His conclusion was supported by *Chakrabarty,* but subject to the three exceptions (law of nature, natural phenomenon, or abstract idea).[272] Judge Linn discussed how the word "new" was used in the statute and related it to the natural phenomenon exception.[273] He found that the basis for excluding scientific principles from statutory subject matter, as described in *Flook*, was "that a scientific principle . . . reveals a relationship that has always existed."[274] Additionally, reference to *Benson* was also useful as it showed that one could not attempt to "monopolize a timeless mathematical relationship among integers, even if the particular representations of the integers may have been new to computer science."[275] This observation would apply to the biological arts as set out in the *LabCorp* discussion.

Judge Linn's discussion of the "useful" requirement of the statute also applied across different technologies.[276] An abstract idea would be too attenuated to be useful, as discussed in *Funk Bros* where the Supreme Court distinguished an unpatentable phenomenon of nature from its application.[277] He also argued that the signal is physical because, just like smoke signals which convey data, the signal must be detectable to successfully signal anything.[278] In fact, he points to *O'Reilly v. Morse*[279] and *The Telephone Cases*[280] for the patentability of signals in which the use of telegraphy to convey Morse code was held to be patentable.[281]

The *Nuijten* decision is interesting as it is the first Federal Circuit decision to discuss statutory subject matter after the *LabCorp*

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270. *In re Nuijten*, 500 F.3d at 1359 n.1 (Linn, J., concurring-in-part and dissenting-in-part).

271. *Id.* at 1362.

272. *Id.*

273. *See id.* at 1363-64.

274. *Id.* at 1364 (alteration in original).

275. *Id.*

276. *See id.* at 1365-67.

277. *See id.* at 1365.

278. *Id.* at 1368.

279. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 124 (1853).

280. Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 572-73 (1888).

281. *See In re Nuijten*, 500 F.3d at 1368-69.

dismissal. It is also illuminating that the majority accepted that the signals would be patentable if stored on a common physical device. This would imply that the Federal Circuit could accept that a biological claim, such as claim 13 in *LabCorp*, would be statutory if it included a routine step or physical device from the prior art, which may be contrary to *Flook*.

The discussion of transformation is also useful as it shows that there are limits on what the Federal Circuit will accept as conveying subject matter utility. In the biological context, that may translate into a requirement for a higher threshold for what would be a transformation. For example, more actual physical steps in lieu of one simple statement for "assaying" may be required to ensure that a transformation is clearly part of the claim. Also, would a non-invasive imaging system cause a transformation if it could assay or detect a result without causing any physical change? It is also useful to see how the Federal Circuit treats the "useful, concrete, and tangible result" test. The dissent states that this test does not require that there be a tangible "thing", but a tangible "result."[282]

C. *In re Comiskey*[283]

This decision was released the same day as *In re Nuijten* and discussed section 101 in a different technical context. "Comiskey's patent application . . . claim[ed] a method and system for mandatory arbitration involving legal documents, such as wills or contracts." [284] According to the application, the claimed "program . . . requires resolution by binding arbitration of any challenge or complaint concerning any unilateral document . . . [or] contractual document."[285]

The Court analyzed the claim and determined that there were no physical devices or computers that were required to perform the process of the independent claims.[286] Also, there was no physical transformation of anything in the claim.[287] They interpreted the claim as mere mental processes or steps and thus unpatentable.[288]

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282. *Morse*, 56 U.S. (15 How.) at 132-33.

283. *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007).

284. *Id.* at 1368.

285. *Id.* (alterations in original).

286. *Id.* at 1369.

287. *Id.* at 1379.

288. *See id.* at 1378-80.

> In other words, the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable

However, the Court chose to single out four dependent claims that recited establishing access through the Internet, software applications, telephone, and cable, among other devices.[289] They stated that an unpatentable mental process may be combined with a machine to render it patentable.[290] They concluded that these claims were statutory subject matter because "[w]hile the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter, these claims in combining the use of machines with a mental process, claim patentable subject matter."[291]

This is an interesting analysis as applied to claim 13 of *LabCorp* where the assaying step could be classified as data gathering, and the correlating step could be classified as mental steps. Following this logic, the *LabCorp* claims would not be patentable, but could be if limited to art recognized physical structure.

This decision has similar issues to *Nuijten*, but different subject matter. It also shows that the Federal Circuit has paid attention to the concerns of the Supreme Court by raising the rejection *sua sponte* at the appeal stage. Again, it is interesting that standard physical devices can provide patentability under section 101. However, the distinction drawn between acceptable physical limitations and incidental usage was whether the physical machine was necessary for, or tied to the operation of the method.[292] The Court also reiterated statements that processes for human thinking, standing alone, were not patentable.[293]

D. Ex parte Jakobsson[294]

Jakobsson's claims were directed to a method, apparatus, and machine readable medium for generating one or more output values of a one-way chain which are used in processor based cryptographic applications such as encryption, decryption, digital signatures,

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> subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable.

Id. at 1378-79.

289. *Id.* at 1379.

290. *Id.* (citing Diamond v. Diehr, 450 U.S. 175, 178-79, 192-93 (1981); AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1355, 1361 (Fed. Cir. 1999); State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1371 (Fed. Cir. 1998)).

291. *Id.* at 1380 (citations omitted).

292. *See id.* at 1379-80.

293. *Id.* at 1377.

294. *Ex parte* Jakobsson, Appeal No. 2006-2107, 2007 WL 1371371 (B.P.A.I. Apr. 16, 2007).

message authentication, user and device authentication, micro-payments, etc.[295] The examiner rejected claims 1 and 20 under 35 U.S.C. § 101 as directed to nonstatutory subject matter.[296]

The Board, citing Supreme Court precedent, stated that it was not always easy to determine whether process claims were statutory subject matter, but that a method may qualify if it was tied to a particular apparatus or changed materials to a different state or thing.[297] The Board referred to Federal Circuit decisions to state that physical transformation, while not a mandatory requirement, is an example of statutory subject matter.[298] The Board also cited other Federal Circuit decisions that indicate that the data transformation step may satisfy this requirement.[299] These decisions held that an electronic heart measurement and the transformation of data into share price both constituted statutory subject matter. The Board stated: "Thus, while *Diehr* involved the transformation of a tangible object - curing synthetic rubber - Federal Circuit also regards the transformation of intangible subject matter to similarly be eligible, so long as data or signals represent some real world activity."[300]

The Board summed up its view of case law relating to the patentability of computer signals:

> Accordingly, our understanding of the precedents at present is: Any computer program claimed as a machine implementing the program (*Alappat, State Street*) or as a method of a machine implementing the program (*AT&T*), is patentable if it transforms data and achieves a useful, concrete and tangible result (*State Street, AT&T*). Exceptions occur when the invention in actuality pre-empts an abstract idea, as in a mathematical algorithm (*Benson*, 409 U.S. at 71-72).[301]

Ultimately, the Board determined that the process claims were not statutory subject matter because they were not limited to any particular technology, apparatus, machinery or end use and they were an attempt to pre-empt all substantial applications of the claimed

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295. *Id.* at *2.

296. *Id.* at *1.

297. *Id.* at *6 (citing Parker v. Flook, 437 U.S. 584, 588 n.9 (1978)).

298. *Id.* at *7 (citing AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1358 (Fed. Cir. 1999).

299. *Id. See also In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc); Arrhythmia Research Tech. Inc. v. Corazonix Corp., 958 F.2d 1053, 1059 (Fed. Cir. 1992).

300. *Jakobsson*, 2007 WL 1371371 at *7.

301. *Id.* at *10.

algorithm which would be a patent on the algorithm itself.[302] The Board made the same conclusion about claims 20 and 21 even though they were written as a machine and medium claims.[303] *Nuijten* and *Comiskey* state that these types of claims are patentable, but *Jakobsson* states that the non-machine part of the claim must still produce a useful, concrete and tangible result.[304]

E. Ex parte Gutta[305]

This decision by the Board of Patent Appeals and Interferences arose as a new ground of rejection at the Board level and therefore is not appealable to the Federal Circuit. The main claim states:

> 1. A method for use in a recommender for evaluating the closeness of two items, each of said items characterized by at least one symbolic feature, said method comprising the steps of:
>
> > [(a)] computing a distance between corresponding symbolic feature values of said two items based on an overall similarity of classification of all instances for each possible value of said symbolic feature values; and
> >
> > [(b)] aggregating the distances between each of said symbolic feature values to determine the closeness of said two items.[306]

The Board entered the new rejection under 35 U.S.C. § 101, as they said that the claim was an attempt to cover an abstract idea.[307] They also stated that it is generally difficult to determine whether a process is an abstract idea since some minor physical steps, such as data gathering or post-solution activity, can be included in the claim to provide the appearance of patentability.[308]

It was determined that "computing" and "aggregating" in independent claims 1 and 10 were mathematical functions and, as such, the methods were disembodied concepts. [309] Mathematical algorithms are nonstatutory subject matter as they represent an attempt to patent the algorithm itself.[310] The Board analyzed the claim

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302. *See id.* at *11-12, § 7.

303. *See id.* at *12-13, § 9-10.

304. *See id.* at *9-11.

305. *Ex parte* Gutta, Appeal No. 2007-1246, 2007 WL 1766997 (B.P.A.I. June 11, 2007).

306. *Id.* at *1.

307. *Id.* at *3-4.

308. *Id.* at *3.

309. *Id.* at *3-4.

310. *Id.* at *3. *See also* Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972); *In re* Castelet, 562 F.2d 1236, 1243 (C.C.P.A. 1977).

to determine if, even assuming that the claims were not solely directed to algorithms, the claim was directed to a practical application of an abstract idea. They cited *State Street Bank* to suggest that the production of a useful, concrete and tangible result equates to a practical application of an abstract idea.[311] However, the Board found no physical matter being transformed, no numerical values being manipulated, and that the methods failed to produce a useful, concrete, and tangible result.[312] Consequently, the Board rejected the claims under 35 U.S.C. § 101 as directed to nonstatutory subject matter.

This decision is another recent example of non-machine implemented claims that are being rejected on new grounds at the Board. Claim 1 was a non-machine implemented algorithm, but claims 19 and 23 required the use of general purpose machines. The Board rejected the non-machine implemented claims for the lack of data transformation. However, it is interesting to note that they also rejected the claims that required the general purpose machine because they did not produce a useful, concrete, or tangible result.[313]

F. Ex parte Glenner[314]

Ex parte Glenner also raised the issue of section 101 as a new ground of rejection.[315] It was decided about nine months after *Bilski*.[316] *Bilski* and *Lundgren* fleshed out the basic issues, but *Glenner* applied the analysis that had developed over the intervening period. The Board discussed the definition of a process, how transformation affected patentability, the three exceptions and the "useful, concrete and tangible result" test.[317] The decision reads more like the application of well settled law than the *Bilski* opinion.

However, Glenner's claims did not just recite a non-machine implemented algorithm.[318] Claims 1 and 23 generally relate to

311. *See Gutta,* 2007 WL 1766997 at *4 (citing . State Street Bank & Trust Co. v. Signature Fin. Group Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998)).

312. *Id.* at *4.

313. *Id.* at *4-5.

314. *Ex parte* Glenner, Appeal No. 2007-1089, 2007 WL 1874818 (B.P.A.I. June 28, 2007).

315. *Id.* at *1.

316. *Compare Glenner*, 2007 WL 1874818, decided on June 28, 2007, *with Ex parte* Bilski, Appeal No. 2002-2257, 2006 WL 4080055 (B.P.A.I. Mar. 8, 2006) decided on March 8, 2006.

317. *See Glenner,* 2007 WL 1874818, at *11-20.

318. *See generally id.* at *1.

browsing media, and specifically to "perform[ing] visual selection and annotation of media objects using intrinsic and extrinsic metadata."[319]

The Court found claim 23 unpatentable:

> Appellants' method claim 23 differs from traditional process claims in several respects. For example, the claim does not recite any particular way of implementing the steps, *nor does it require any machine or apparatus to perform the steps.* In addition, the method claim does not recite any electrical, chemical, or mechanical acts or results, which are typical in traditional process claims. Finally, the claim does not call for any *physical transformation* of an article to a different state or thing. While claim 23 does perform a *transformation of data* by "combining a subset of the media objects to generate a new media object," *it does not require any machine or apparatus to perform the steps.* The question of whether any of these distinctions takes claim 23 outside the realm of patent-eligible subject matter has never been squarely addressed by the Federal Circuit. Appellants' claims are not the type of method that the Supreme Court or Federal Circuit has ever found patentable under section 101.[320]

The Board reached back to old Supreme Court precedent like *Benson* and *Diehr*, but also discussed pre-*State Street Bank* and *AT&T* Federal Circuit decisions and even cited to the *LabCorp* dissent as support for requiring machines to be necessary and recited in the claims.[321] However, the primary focus of the opinion was on *In re*

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319. *Id.* Specifically, they claim:

> 1. A media generation system comprising:
> a component that receives a plurality of media objects;
> a component that annotates the plurality of media objects with at least a subset of metadata;
> a component that generates at least one new media object *via* combining a subset of the media objects based at least in part upon the metadata associated therewith; and
> a component that embeds a first media object into a second media object.
>
> 23. A method of editing media to generate new media comprising:
> receiving a plurality of media objects, at least a portion of which are annotated with metadata;
> identifying the metadata;
> combining a subset of the media objects to generate a new media object, the combining being based at least in part upon the identified metadata; and
> embedding a first media object into a second media object.

Id.

320. *Id.* at *11.

321. *See id.* at *10-20.

Schrader[322] where the Board rejected the idea that a process claim could be patentable even if it did not transform an article or thing.[323] The Board distinguished *State Street Bank*, *AT&T*, *Arrhythmia* and *Alappatt* by stating that these decisions required data transformation and that there was no transformation in these claims.[324] This latest opinion by the Board stands for the premise that a process claim will not be patentable, even though it is useful, if it does not transform an article or thing, such as by a machine.[325]

G. Classen v. Biogen[326]

Classen raises the issue of statutory subject matter in a biological context similar to the issues that were dismissed in the *LabCorp* Supreme Court appeal. The section 101 issues have been vetted by the parties throughout the litigation and that should obviate the procedural problem encountered in *LabCorp*.[327]

Classen Immunotherapies "developed and patented methods for evaluating and improving the safety of immunization schedules."[328] The company holds U.S. Patent Nos. 6,420,139, 6,638,739, 5,728,385, and 5,723,283 directed to these inventions.[329] Classen alleged that a large group of defendants infringed the patents by "examining the correlation between vaccination schedules and the risk of developing chronic immune mediated disorders; and . . . [then] by using the results of that study to develop [new] vaccination protocols."[330] The District Court for the District of Maryland, Northern Division dismissed the infringement claims and Classen requested reconsideration.[331] One of the issues was whether the claims at issue were directed to statutory subject matter under 35 U.S.C. § 101.[332] A representative claim of U.S. Patent No. 5,723,283 is:

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322. *See id.* at *14-16; *In re* Schrader, 22 F.3d 290 (Fed. Cir. 1994).

323. *See Glenner*, 2007 WL 1874818, at *14 & n.7. Footnote 7 discussed *AT&T* which called *Schrader* "unhelpful" because it did not reach the question whether a "useful, concrete, and tangible" result occurred.

324. *See id.* at *13-14.

325. *See id.* at *15.

326. *See* Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Civ. No. WDQ-04-2607 (D. Md. Aug. 16, 2006).

327. *See id.*

328. *Classen*, Civ. No. WDQ-04-2607, slip op. at 2.

329. *Id.*

330. *Id.*

331. *Id.* at 2-3.

332. *See id.* at 9-12.

> 1. 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 immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and 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.[333]

The defendant argued that the claim was "unpatentable because [it] involve[d] 'thinking about' whether a vaccination schedule reduce[d] the incidence of chronic disease and [was]. . . an abstract mental process about a natural phenomenon."[334] The Court looked at the '283 patent claim above, stated that the correlation was a natural phenomenon, and determined that the question was "whether the . . . patents simply describe[d] the correlation."[335] The Court went on to state that the '283 claim described a general inquiry about the correlation and was "indistinguishable from the idea itself."[336] The patents did not describe a particular vaccine or schedule and were little more than an inquiry into the extent of the correlation.[337] With respect to the '139 and '739 patents, the Court added "[a]s it would appear that the 139 and 739 patents are an indirect attempt to patent the idea that there is a relationship between vaccine schedules and chronic immune mediated disorders, the Court finds they are an attempt to patent an unpatentable natural phenomenon."[338]

The Court did not discuss whether the claimed process transformed an article into a different state or thing, which may have led to a conclusion of patentable subject matter under prior case

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333. U.S. Patent No. 5,723,283 col.51 ll.50-60 (filed May 31, 1995). The defendants raised the defense set out in 35 U.S.C. § 271(e)(1). *See generally* Corrected Brief for Defendant-Appellee Biogen IDEC , Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Nos. 2006-1634, -1649 (Fed. Cir. Feb. 28, 2007), 2007 WL 869894 [hereinafter Biogen Brief]; Corrected Brief for Defendant-Appellee Glaxosmithkline, Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Nos. 2006-1634, -1649 (Fed. Cir. Feb. 28, 2007), 2007 WL 869893 [hereinafter GSK Brief].

334. Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Civ. No. WDQ-04-2607, slip op. at 10-11 (D. Md. Aug. 16, 2006).

335. *Id.* at 11.

336. *Id.*

337. *Id.* at 12.

338. *Id.*

law.[339] However, that issue was more fully developed in the Briefs on appeal to the Federal Circuit.[340]

Classen argued to the Federal Circuit that the claims were not invalid for containing a mental step or scientific truth and that the Supreme Court interpreted the four statutory classes in section 101 to include anything made by man.[341] Next, Classen stated that the claimed method "when evaluated as a whole results in a tangible result: [which is] the selection of a lower risk schedule and the resultant vaccination of children in accord with that schedule."[342] Classen stated that the claims do not pertain to "thinking about" a schedule, instead they related to choosing an immunization schedule.[343]

Claim 1 of the '283 patent suggests that the active step of "immunizing" requires a transformation in a mammal because an immunogen must be delivered into the body of a mammal and the immune system typically responds to transform the mammal in some way. However, it appears that Classen interpreted the claims more broadly to require only a comparison between immunization schedules, and not the physically active immunization step.[344] Classen was effectively removing the transformation step by stating that comparing results between previous studies and then designing an immunization schedule was infringement. This position puts their statutory subject matter argument on more tentative ground given the development of the case law and the dissent in *LabCorp*.

Defendant Merck argued in their Reply brief that the Classen claims do not require physical steps even though they are limited to immunizing.[345] They asserted that one can infringe the Classen claims by reading the results of a previous vaccination study and thinking

339. *See generally id.* at 9-12.

340. *See* Reply Brief of Appellant at 10-13, Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Nos. 2006-1634, -1649 (Apr. 10, 2007), 2007 WL 1571347 [hereinafter Classen Reply Brief]; GSK Brief, *supra* note 333, at 26; Brief for Defendant-Cross Appellant Merck & Co. at 39, Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Nos. 2006-1634, -1649 (Jan. 16, 2007), 2007 WL 460138 [hereinafter Merck Brief].

341. Corrected Brief for Appellant Classen Immunotherapies, Inc. at 35, Classen Immunotherapies, Inc. v. Biogen IDEC, et al., Nos. 2006-1634, -1649 (Fed. Cir. Nov. 20, 2006), 2006 WL 3846638 [hereinafter Classen Brief].

342. *Id.* at 36.

343. *Id.*

344. *See generally* Classen Brief, *supra* note 341, at 6-7, 12, 40-41; Merck Brief, *supra* note 340, at 12.

345. *See* Merck Brief, *supra* note 340, at 1-2.

about the application of those results.[346] They claimed that the only difference between the prior art and the Classen invention is the thought process.[347] Simply adding immunization to the claim is not enough to make it patentable under 101, citing *Flook*.[348]

Clearly, Merck aims to show that the issues here are the same as the issues that appeared to be unpatentable in *LabCorp* as outlined by Justice Breyer. The Supreme Court should agree that simply thinking about an immunization schedule is non-statutory and that some physical steps will be required. *Comiskey* supports this view by requiring some physical structure in a claim.

Classen also argued in their reply brief that the court should determine whether the applicant is seeking to patent a formula in the abstract and not simply ask whether an article is transformed or reduced because that test is only one example of a patentable process.[349] They cited *Diehr* for this proposition, but the claims in *Diehr* were more active process steps which involved molding rubber.[350] The software component was one step in the overall process of molding rubber, whereas in *Classen* there do not seem to be any physical steps that are similar. The above exemplary claim from '283 is not limited to risk assessment and vaccination. As Classen appears to interpret it, the claim encompasses simply picking a schedule. However, this is similar to an algorithm, which can be unpatentable as an abstract idea or mental steps. Also, Classen argued that the laws of nature must be classic algorithms, like $E=mc^2$, and vaccination schedules were not such a mathematical formulation.[351] However, *Ex parte Jakobsson* stated that claims do not need to recite a specific algorithm to be unpatentable.[352]

In looking at the algorithm and signals decisions above, in relation to *Classen v. Biogen*, one can see that once the Court finds that the claim is directed to an algorithm, it looks for a transformation or a practical application on a machine.[353] The same is true for the

346. *See id.* at 2.

347. *Id.* at 14-15.

348. *See generally id.* at 36 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)).

349. *See* Classen Reply Brief, *supra* note 340, at 11.

350. *Id. See also* Diamond v. Diehr, 450 U.S. 175, 192-93 (1981).

351. Classen Brief, *supra* note 341, at 37.

352. *Ex parte* Jakobsson, Appeal No. 2006-2107, 2007 WL 1371371, at *12 (B.P.A.I. Apr. 16, 2007).

353. *Benson* did not hold that a machine was necessary to convey patentable subject matter to an algorithm or that a claim would have to comply with all of their prior precedents. *See* Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972).

LabCorp dissent.[354] Also, the implication at the Supreme Court is that a useful, concrete and tangible result may not suffice to classify a claim as statutory subject matter. *Classen* can be said to fail the transformation analysis, given their claim interpretation. Again, using the *Classen* interpretation, the claims would cover the review of preexisting data (mental steps or thinking) of vaccination schedules and it is unlikely that this analysis would be classified as providing a useful, concrete and tangible result.

From these post-*LabCorp* decisions, we can derive the following:

- The Interim Guideline approach is a reasonable analysis, including the "useful, concrete, and tangible result" test.[355]

- Being physical is not enough. The matter in the claim may need to meet other thresholds such as being tangible, substantial, and permanent, to fit into a statutory category.[356]

- Claims may be patentable if tied to a general purpose machine. Data gathering is not a step that will convey patentability without some key link to the process. Patentability will be more difficult as one moves away from any physical structure. Human thinking, without something more, will not be patentable.[357]

- Claims do not need to recite a particular algorithm to be unpatentable. The claimed subject matter will still need to satisfy the useful, concrete, and tangible result test.[358]

- Simply reciting storage medium for algorithm will not necessarily convey patentability as the claims must still satisfy the useful, concrete, and tangible result test.[359]

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354. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (Breyer, J., dissenting).

355. *Ex parte* Bilski, Appeal No. 2002-2257, 2006 WL 4080055 (B.P.A.I. Mar. 8, 2006).

356. *In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007).

357. *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007).

358. *Ex parte* Jakobsson, Appeal No. 2006-2107, 2007 WL 1371371 (B.P.A.I. Apr. 16, 2007).

359. *Ex parte* Gutta, Appeal No. 2007-1246, 2007 WL 1766997 (B.P.A.I. June 11, 2007).

- Some questions arise regarding the vitality of the useful, concrete, and tangible result test and it is unclear how to define those terms.[360]

V. TESTS FOR STATUTORY SUBJECT MATTER

This article addresses the scope of patentability under 35 U.S.C. § 101. The development of what defines a patent began during the transition between a system where patents were granted based on privilege, to a system where patents are granted based on merit. During that time, it became evident that patents should be awarded to those who had an invention that was new and properly described. The requirements for novelty and non-obviousness are codified in 35 U.S.C. §§ 102 and 103, while the description requirements are codified in 35 U.S.C. § 112. Section 101 defines what types of subject matter may be patented if one satisfies all other criteria.

To be patentable, § 101 requires that the potential invention fit into one of the four defined classes of proper subject matter as the first part of any test. They include: a process, machine, article of manufacture or composition of matter.[361] In most areas, it may be a relatively easy task to assign an invention to one of these classes, but in other technical areas it is difficult to determine whether an invention fits into one of the statutory categories.[362] The analysis has been likened to the idea/expression dichotomy in copyright law, which recognizes that the expression of an idea may be protected by copyright, but that the idea itself cannot be copyrighted.[363] However, over time, case law has provided us with some tests which have been recently interpreted by various judicial forums from the Patent Office to the Supreme Court. Tests will be discussed with reference to biological and diagnostic claims since this is the focus of the present article.

The policies underlying future tests for patentable subject matter in the biological context can be seen in the dissent by Justice Breyer in *LabCorp*, which represents the ideas of at least three members of the Court.[364] The general concerns lie in the tension between

360. *Ex parte* Glenner, Appeal No. 2007-1089, 2007 WL 1874818 (B.P.A.I. June 28, 2007).

361. 35 U.S.C. § 101 (2000).

362. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926 (2006) (Breyer, J., dissenting).

363. *See* Public Patent Found. Brief, *supra* note 151, at 12-13.

364. *See Lab. Corp.*, 126 S. Ct. at 2922 (Breyer, J., dissenting).

encouraging research and development versus diminished incentives when the system is overprotective.[365] More specifically, the dissent did not want to give a monopoly on the basis of a scientific factor that would foreclose other beneficial experimentation.[366] Justice Breyer also did not want to stop people from testing, publishing scientific work, thinking about scientific relationships, or sharing scientific information.[367] The dissent was interested in a test that would provide the proper framework to encourage, but not impede research.[368]

Anyone drafting claims to biological subject matter will need to address the policies taken from the above case law during prosecution or litigation.[369] For example, after assigning the invention to one of the four statutory classes, a drafter will need to answer several questions: was there anything physical or tangible in the claim or did it involve an exception to patentability, such as a mental step, abstract idea, or a law of nature? Was there a tangible physical or chemical transformation? Was the process for transforming an article the focus of, or tied to the claim or was transformation incidental? Was there a preemption of all possible uses for a method claim? These are important issues, and clearly the tangible, physical element is a central theme that can change a claim from mere abstraction and unpatentable to an application and patentable.

The dissent in *LabCorp* criticizes some of the existing tests set forth in case law, including the "useful, concrete, and tangible result" test.[370] At least one Board decision discussed above has also questioned the test. However, the Federal circuit still determines whether the subject matter is tangible.[371]

Given this recent jurisprudence, claim limitations should be added to ensure that section 101 will be satisfied when reviewed by the PTO or a court. Practitioners can include tangible, physical devices or physical, chemical, or perhaps even data transformations. The physical devices or transformations should relate to the inventive aspect of the device to avoid the issues raised in *Flook* and to ensure that the inventive aspect is considered as part of the whole invention as in *Diehr*. Obviously, inserting additional claim limitations can

365. *See id.*
366. *See id.*
367. *See id.*
368. *See id.*
369. *See id.* at 2927-28.
370. *See id.* at 2928.
371. *See In re* Nuijten, 400 F.3d 1346, 1356-57 (Fed. Cir. 2007).

create concerns for infringement and biological or diagnostic claims can present special issues due to the possibility that the claim will be performed by more than one entity. For example, it is typical that different entities will collect, process or analyze the biological sample. Therefore, a practitioner will need to consider which steps will satisfy section 101 while providing reasonable coverage for the invention. Only those steps that will be associated with one entity should be included in the claim.

Even though a tangible, physical element may be claimed in a process, that element must not claim all substantial uses as it would essentially negate the limiting nature of the element to render it useless. The *LabCorp* dissent found that claim 13 violated that prohibition irrespective of the physical transformation step. One important question is how this issue may apply to single or multiple claims. If the drafter simply divides up all the known ways to perform the transformation into multiple claims, will all substantial uses be analyzed for each claim, or for the entirety of the patent? It may be logical to apply the analysis to all claims as a whole.

The PTO has proposed its own internal test for what is patentable in their "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (the "Guidelines").[372] The Guidelines were published on November 22, 2005, so they have not incorporated more recent developments in the law.[373] However, they covered much of the same territory. For example, they require that the examiner first look at the claim as a whole and see what category the claim recites (process, machine, manufacture, or composition of matter).[374] The next step is to check for any of the three exceptions to patentability (abstract idea, law of nature, or mental steps).[375] Then, the Guidelines ask if there is a practical application, such as a physically transformation or a useful, concrete, and tangible result.[376] Finally, the Guidelines require that the examiner determine if the claims cover all substantial uses of the exception to patentability.[377] These Guidelines are the internal rules of the patent office and do not have the force of law, but they are derived from the relevant decisions discussed above. One difference to note is

372. *See* Interim Guidelines, *supra* note 228.
373. *See id.*
374. *Id.* § IV (B).
375. *Id.* § IV (C).
376. *Id.* § IV (C)(2).
377. *Id.* § IV (C)(2)(b)(3).

the *LabCorp's* dissent where the "useful, concrete, and tangible result" was questioned in light of prior Supreme Court precedent.[378]

VI. PRACTICAL EFFECTS

As several of the *LabCorp* Amicus briefs indicated, the potential effect on patents could be significant as there are many issued claims that follow similar formats. Typical claims in diagnostic settings include the following example language:

> A method for diagnosing disease X, comprising the steps of: a) determining a level of Y and b) comparing the level of Y determined in step a) with a normal level of Y from control subjects, wherein (i) normal level or lower than normal levels of Y indicates absence of disease X; and (ii) higher than normal level of Y indicates the presence of disease X.

> A method for diagnosing increased risk of disease X in a human subject, comprising the steps of: investigating the presence of a target gene, wherein said target gene encodes a polypeptide comprising the sequence of SEQ ID NO: 1; and diagnosing increased risk of disease X when the presence of the target gene is not detected.

The above method claims arguably do not contain anything tangible or a physical transformation and can be open to challenge under current case law. However, given some comments in the *LabCorp* briefs, there may be limits that could be added in the sample collection or sample preparation steps to create a physical transformation. Some example limitations in these, and other diagnostic claims include: mixing; contacting, inoculating, vaccinating, changing the charge, attaching a group, detecting a physical change, chemically altering, extracting compound x and analyzing the level in serum, contacting a body fluid with a device for assaying compound x, mixing a body sample with a reagent designed to determine the level of x, mixing a fluid body sample in a device that assays the level of x; contacting a body sample with an instrument that can assay the level of x.

Additionally, the claim could be limited with the use of a specific physical device to perform the claimed process, such as "detecting with an instrument capable of . . . ." Additionally, the claim could be cast as a physical structure, such as a computer

378. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2928 (2006) (Breyer, J., dissenting).

medium. For example, "assaying for the level of compound x, storing the level in a data processing storage medium, calculating the level of x, correlating the level of x with an indication of disease y, or calculating the level of x and storing the results a computer storage medium, inputting values indicative of the level of x, storing them, correlating the levels to a disease state . . . ." These limitations are simple examples and there are many more. They may be added to claims to provide utility under section 101, but only in accordance with the precedents above.

Ultimately, the drafter must determine what limitations need to be added to any process claim to provide a tangible, physical transformation or structure and how to avoid claiming all substantial uses of the transformation. Much of this analysis will be factually dependant on the invention.

VII. CONCLUSION

Defining statutory subject matter is a hard task for new technologies, but is also difficult for existing technologies, such as in diagnostics. Tension exists between protecting invention to encourage innovation and stifling invention through overprotection. However, care must be taken that corrective actions do not selectively affect certain industries over others, as may happen with biological or diagnostic claims. Good policy reasons support both sides of the debate, including the policy that the law should encourage new technologies, as it did for biotechnology and computer programs. Supreme Court decisions show how difficult it is to make this determination as the Justices have been closely divided in many of the decisions discussed above.

The language of section 101 sets out four broad classes for what is patentable and case law has established various tests to assign a claimed invention to a class. Those tests are discussed above, but one key requirement is the injection of something physical (such as a transformation or a device) into the claimed subject matter. With something physical, the invention may be patentable as an application of a law of nature, not unpatentable as claiming only the law itself. Even though there is a physical element in the claim, two additional criteria should preferably be met: it should not cover all substantial uses of the law of nature and any physical limitation should be tied to the method being claimed.

The courts at all levels are interested in this analysis. The Board of Appeals is rejecting more claim types based on section 101 and

seems to be reading prior case law in a limiting fashion. The Federal Circuit is developing a more conservative view as well but has not changed its prior decisions expanding the doctrine, as it did in *State Street Bank* and other cases. The Supreme Court has shown an interest in this issue and it is expected that they will seek another vehicle to test what patentable under section 101. We will need to wait to see if the *LabCorp* dissenters will find two other Justices to join their position.

What may happen when the Supreme Court hears the next case relating to biology is getting clearer, but open questions remain. Will they eliminate the useful, concrete, and tangible result test? Will they seek to push the law back to *Flook* to require that any law of nature limitation be non-obvious on its own? Will they strike down existing tests and posit new tests? The answers to all of these questions may be unclear, but what is clear is that there will be some opportunities to revisit the issue in the next year or so and there is a more conservative mood in determining the scope of intellectual property rights.

Given the case law development and legal environment surrounding intellectual property, it would appear that this doctrine is contracting like many other areas of patent law. Non-computer implemented methods are not patentable and we will probably see a challenge to those claims as implemented on computers or other physical devices. Also, there may be a modification or rejection of the useful, concrete and tangible result test. As to the biological and diagnostic types of claims, it is unclear in what direction case law will develop to affect those issued patents. There will still be a requirement to have a physical element, such as a transformation or a device, but how far can one go in achieving claims of significant breadth is yet to be determined. We will probably see a review of the difference between *Flook* and *Diehr* so that the claim elements other than the law of nature may be the focus of what is patentable. Whatever the outcome, it would seem that these changes will come relatively soon given the judicial interest in looking at this issue at all levels.