



**Patentability of scientific principles and natural relationships in the light of  
Laboratory Corp. v. Metabolite**

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## **Introduction**

The scope of patentable subject matter in USA can be considered to be the broadest in the world. The US patent system has been responding to new technologies faster than that of any other country. It was the first to open its gates to patentability in fields such as Biotechnology, Information Technology or Business Methods. The adaptive and flexible nature of the patent regime in USA can be attributed to the open language used under section 101 of Title 35, which relates to patentable subject matter and the lack of exclusions from patentability except for the judicially created exceptions such as abstract ideas, physical phenomena and laws of nature. Though it is believed that a wide scope of patentable subject matter has helped US move ahead of the rest of the world in cutting edge technologies because of support from patent incentives, it has given rise to various controversies resulting in a defining body of case law. The US Supreme Court was asked to decide the scope of subject matter in the light of judicial exceptions from time to time. Recently, it was confronted with such an issue in the Laboratory Corp. case, which decision the patent scholars believed would have a profound impact on the scope of patentability in relation to natural laws and scientific principles. Though the US Supreme Court dismissed the case, it can still be considered to be an important decision in patentability jurisprudence. This article discusses the patentability of natural laws and scientific principles in the light of the Laboratory Corp. case.

## **I. Patentability and scientific principles/natural laws**

In USA, patents are available to processes, machines, manufactures, compositions of matter and improvements, which are not physical phenomena, laws of nature, scientific principles or abstract ideas. By excluding scientific principles, laws of nature, etc., from the scope of patentability, the patent system makes such laws and principles available to the public and encourages progress of science and technology through free implementation of such principles or laws in specific inventions. It is believed that grant of patents over scientific principles or laws of nature, etc., would preempt them from the public and therefore, impede the progress of science and technology. While the basic rule

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is lucid, the line demarcating a scientific principle and its specific application is not clear. Though the Supreme Court has made various attempts to clarify the issue, there is still ambiguity and uncertainty in determining the stage at which a scientific principle or natural law manifests as a specific application and becomes patentable. Some important US Supreme Court cases relating to the issue are discussed below:

#### A. O'Reilly v. Morse

In *O'Reilly v. Morse*, the Supreme Court held that Morse's claim over his electromagnetic telegraph was not valid as he claimed the broad principle of printing characters at a distance rather than the specific application of the principle.<sup>2</sup> Morse tried to claim use of the motive power of the electric or galvanic current, which is called electro-magnetism, however developed, for making or printing intelligible characters, signs or letters at any distance.<sup>3</sup> While rejecting his patent, the court stated that the discovery of a principle of natural philosophy or physical science is not patentable.<sup>4</sup> As Morse claimed a patent, for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it, the US Supreme Court held Morse's patent to be invalid as he was claiming a principle.<sup>5</sup>

#### B. Gottschalk v. Benson

In *Gottschalk v. Benson*, a patent on the method for converting binary-coded-decimal (BCD) numerals into pure binary numerals for use with general purpose digital computer of any type was held to be not patentable as it was a general principle and did not involve any specific application.<sup>6</sup> The court in this case stated that a principle, in the abstract, is fundamental truth, an original cause, a motive, and laws of nature cannot be patented, as no one can claim an exclusive right in any of them. It went on to state that any specific application of a law of nature is patentable. The court further observed that while a scientific truth, or the mathematical expression of it is not a patentable invention, a novel and useful structure created with the help of knowledge of scientific truth may be patentable.<sup>7</sup> As the claims in the case were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use; and as they purported to cover any use of the claimed method in a general-purpose digital computer of any type, the court held that the patent as invalid.<sup>8</sup> Furthermore, as the invention claimed is abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion, the court held the invention to be not patentable.<sup>9</sup>

#### C. Parker v. Flook

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<sup>2</sup> *O'Reilly v. Morse*, 56 U.S. 62 (U.S., 1853).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Gottschalk v. Benson*, 409 U.S. 63, 93 S.Ct. 253 (1972).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

In *Parker v. Flook*, the patent application described a method of updating alarm limits.<sup>10</sup> In essence, the method consisted of three steps: an initial step which merely measures the present value of the process variable (e.g. the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value. The only difference between the conventional methods of changing alarm limits and that described in the patent application rested in the second step, namely the mathematical algorithm or formula. Using the formula, an operator can calculate an updated alarm limit once he knows the original alarm base, the appropriate margin of safety, the time interval that should elapse between each updating, the current temperature and the appropriate weighting factor to be used to average the original alarm base and the current temperature.<sup>11</sup>

In this case, the court reiterated that scientific principles are not patentable as patent laws have not been fundamentally designed to protect them. However, the court observed that the line between a patentable invention and an unpatentable "principle" is not always clear as both are conceptions of the mind, seen only by their effects when being executed or performed.<sup>12</sup> It went on to hold that the mathematical formula involved in the case had no substantial practical application except in connection with a digital computer and is therefore not patentable as scientific principle.<sup>13</sup> The court feared that allowing the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.<sup>14</sup> It observed that the underlying notion is that a scientific principle, such as that expressed in the patent application, reveals a relationship that has always existed. The court concluded that an already existing relationship is not patentable because in granting patent rights, the public must not be deprived of any rights that it freely enjoyed.<sup>15</sup>

#### D. *Diamond v. Diehr*

*Diamond v. Diehr* related to patentability of a patent application claiming invention for a process for molding raw, uncured synthetic rubber into cured precision products by using a mathematical algorithm.<sup>16</sup>

The court in this case observed that a claim reciting a mathematical formula or scientific principle or phenomenon of nature in the abstract was not patentable. It further stated that a mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of the patent for the formula to a particular technological use.<sup>17</sup> It further stated that when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect, e.g., transforming or reducing an article to a different state or thing,

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<sup>10</sup> *Parker v. Flook*, 437 U.S. 584, 98 S.Ct. 2522 (1978).

<sup>11</sup> *Id.* at 586.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 588.

<sup>16</sup> *Diamond v. Diehr*, 450 U.S. 175, 101 S.Ct. 1048 (1981).

<sup>17</sup> *Id.* at 177.

then the claim satisfies the statutory requirements for possible patentable subject matter.<sup>18</sup> Finally, the court held that the process as a whole is patentable as the patent applicant had claimed a specific application of the mathematical formula and not the formula itself.

#### E. Funk Bros. v. Kalo Inoculants

Funk Bros. case relates to the patentability of an inoculant for leguminous plants comprising a plurality of selected mutually noninhibitive strains of different species of bacteria of the genus *Rhizobium*.<sup>19</sup> The court analyzed patentability of the invention based on the exclusion relating to laws of nature. It stated that the inventor does not create state of inhibition or of non-inhibition in the bacteria, which are the works of nature.<sup>20</sup> It held that these qualities are not patentable because patents cannot be issued for the discovery of the phenomena of nature.<sup>21</sup>

It went on to state that the qualities of the *Rhizobium* bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men, which are manifestations of laws of nature, free to all men and reserved exclusively to none.<sup>22</sup> The court further stated that discovery of an unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.<sup>23</sup> As per the court, if there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.<sup>24</sup> It observed that allowing a patent over the bacteria would amount to patent over an ancient natural principle, which has been disclosed by the inventor.<sup>25</sup> In the light of the aforementioned reasoning, the court concluded that aggregation of species fell short of invention within the meaning of the patent statutes.

#### F. Diamond v. Chakrabarty

In *Diamond v. Chakrabarty*, a case relating to patentability of a genetically modified *Pseudomonas* bacterium capable of degrading oil spills, the US Supreme Court held that the bacterium is patentable as its creation involved a hand of man.<sup>26</sup> It stated that while laws of nature, physical phenomena, and abstract ideas are not patentable, the *Pseudomonas* bacterium was not an unknown natural phenomenon, but a nonnaturally occurring manufacture or composition of matter, which is a product of human ingenuity having a distinctive name, character and use.<sup>27</sup> In this case, the court drew the line between patentable inventions and laws of nature based on the involvement of the hand of man. If a hand of man is involved, the invention is not naturally existing and would therefore be patentable.

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<sup>18</sup> *Id.*

<sup>19</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440 (1948).

<sup>20</sup> *Id.* 131.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204 (1980).

<sup>27</sup> *Id.* at 310.

It can be concluded from the aforementioned decisions of the Supreme Court that laws of nature, scientific principles, physical phenomena and abstract ideas are not patentable. As per the court, discovery of a scientific principle or unknown law of nature would not be eligible for patent protection. In order to be patentable, an invention should be a practical application of a scientific principle or natural law to a new and useful end. An invention will be considered to be non-natural if it involves a hand of man in its creation. While the basic rule is clear, the test for differentiating a scientific principle or law of nature from an invention which is patentable is not clear.

## II. Laboratory Corp. v. Metabolite

### A. Case history

The patent at issue in the case relates to methods for detecting Cobalamine (Vitamin B12) and Folate (Folic Acid) deficiency by determining the levels of homocysteine in the body.<sup>28</sup> The claim in question claims a method for detecting a deficiency of cobalamine or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine and correlating the values to an elevated level of total homocysteine in said body fluid with a deficiency of cobalamine or folate.<sup>29</sup>

The successor of University Patents Inc. (the patent holder), Competitive Technologies Inc., licensed the patent to Metabolite which in turn sublicensed the patent to Roche Biomedical Laboratories (now Lab Corp).<sup>30</sup> Lab Corp. exercised the licensed patent and paid royalties under the License to Metabolite.<sup>31</sup> For some time, LabCorp performed total homocysteine assays under the sublicense.<sup>32</sup> However, after a while, it switched to a total homocysteine assay developed by Abbott Laboratories and discontinued royalty payments to Metabolite for total homocysteine assays.<sup>33</sup>

In response, Metabolite sued LabCorp for infringement in the District Court of Colorado. The district court held that LabCorp was liable for contributory infringement and granted damages to a tune of seven million dollars. The court said that the doctors by co-relating levels of homocysteine to Vitamin B deficiency infringed claim 13 of the patent. As Lab Corp. supplied the data to make such an analysis, it said that Lab Corp. was liable for contributory infringement. During the proceedings, Lab Corp. argued that claim 13 was not valid because it claims a scientific principle, i.e. the relationship of homocysteine to cobalamine and folic acid deficiency and not a specific method based on it. The court rejected this argument and stated that the claim is not a scientific principle. The Federal Circuit upheld the decision of District Court on validity of the patent claim and infringement by Lab Corp.

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<sup>28</sup> U.S. Patent No. 4,940,658.

<sup>29</sup> Claim 13 of the Patent.

<sup>30</sup> *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354 at 1359 (C.A.Fed. (Colo.), 2004).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

The US Supreme Court accepted the writ of certiorari filed by Lab Corp., challenging the decision of the Federal Circuit on validity of claim 13 of the patent. The question to be decided by the court was "Whether a vaguely worded patent claim "directing a party simply to correlate test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."<sup>34</sup>

## **B. Arguments and Issues**

About eighteen Amici briefs were filed by different parties in addition to briefs of petitioner and respondents. The briefs pointed out different issues involved in the case.

### ***Arguments of the petitioner (Laboratory Corp. Inc.) and Amici supporting the petitioner***

The petitioner and Amici in support of the petitioner argued in their briefs that claim 13 of the patent was not valid as it was a product of nature.<sup>35</sup> They argued that the correlation of homocysteine with cobalamine and folic acid was a biological relationship that forms a part of the laws of nature and therefore not patentable. The petitioner further submitted that allowing a patent on a basic medical correlation would have grave implications in the medical field and beyond, because if Claim 13 is upheld, any person who discovers a new correlation useful in medicine would gain the right to demand royalties from people who think or tell others about it, thereby discouraging researchers from developing new testing methods and chilling medical practice, future discovery, and scientific discourse.

“Patients not Patents” argued that as neither mental processes nor natural phenomena were patentable subject matter, the claim was invalid and that upholding the claim would lead to a proliferation of patents for purely mental processes, which would in turn harm both individual patients as well as public health<sup>36</sup>. Affymetrix Inc. and Jon Barton of Stanford argued that upholding broad claims such as claim 13 would impede progress of research by blocking basic scientific principles.<sup>37</sup> They also argued that DNA and Genomic research would be hit in a big way if such patents are allowed.

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<sup>34</sup> Petitioner's Brief.

<sup>35</sup> Brief for the petitioner, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL 3543099, Supreme Court of the United States.

<sup>36</sup> Brief of Patients not Patents, Inc., as Amicus Curiae, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL

<sup>37</sup> Brief for Amici Curiae Affymetrix, Inc. and Professor John H. Barton, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL 3597814.

The American Medical Association argued that holding claim 13 valid would impede the sound practice of medicine.<sup>38</sup> American Clinical Laboratory Association argued that holding claim 13 valid would prevent doctors from using the results of any laboratory assays, even the ones not covered by the patent because the claim very broadly covers a scientific relationship.<sup>39</sup> American Heart Association argued that upholding claim 13 would grant an exclusionary right that would prevent doctors from properly diagnosing and treating cardiovascular diseases in their patients, not to mention other disorders - including cobalamine (vitamin B12) deficiency itself.<sup>40</sup> They further submitted that it would forbid physicians from following the American Heart Association's published Science Advisory for physicians in the course of patient treatment.

### ***Arguments of Respondent (Metabolite) and Amici in its support***

Respondent and Amici in its support argued that claim 13 has to be declared as patentable subject matter because it falls outside the scope of laws of nature and natural phenomena.<sup>41</sup> They also argued that the issue cannot be decided by the US Supreme Court as it was not raised before the trial court. The Respondent further argued that claim 13 sets forth a practical application of the Inventors' discovery that elevated total homocysteine levels correlate with cobalamin or folate deficiencies.<sup>42</sup> The process necessarily involves the physical transformation of a body fluid, and that alone means that the claimed process is patentable subject matter. It also argued that the patent does not claim all practical applications of the correlation between elevated total homocysteine and vitamin deficiencies because there are a number of important uses of that correlation that do not infringe the patent.<sup>43</sup>

AIPLA and Federal Circuit Bar Association argued that the scope of patentable subject matter should be construed broadly to promote rapid progress of technology, especially in fields such as biotechnology and diagnostic medicine.<sup>44</sup> Perlegen Sciences, Inc., Mohr, and Davidow Ventures argued that claim 13 as a whole performs a useful function - employing body fluid to diagnose deficiencies that neither the assay step nor the

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<sup>38</sup> Brief for the American Medical Association, the American College of Medical Genetics, the American College of Obstetricians and Gynecologists, the Association for Molecular Pathology, the Association of American Medical Colleges, and the College of American Pathologists as Amici Curiae, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL 3597812.

<sup>39</sup> Brief of the American Clinical Laboratory Association as Amicus Curiae, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL 3543098.

<sup>40</sup> Brief of the American Heart Association as Amicus Curiae, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2005 WL 3561169.

<sup>41</sup> Brief for Respondents, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2006 WL 303905.

<sup>42</sup> Brief of Amicus Curiae Boston Patent Law Association, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2006 WL 303909.

<sup>43</sup> American Intellectual Property Law Association (AIPLA)

Amicus Curiae Brief of the Federal Circuit Bar Association, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2006 WL 303906 and<sup>44</sup> Amicus Curiae Brief of American Intellectual Property Law Association, *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 2006 WL 303907.

correlation step alone could perform. This diagnostic tool is made by man because, in nature, it is impossible to diagnose such deficiencies through unaided inspection of body fluid. Even assuming that the correlation step is a natural law, the result of the process, a medical diagnosis, is not.<sup>45</sup> They further argued that as claim 13 is self-limited to assays of body fluid, not body tissue, it does not preempt every substantial application of the asserted natural law. They also submitted that if the Court holds the subject matter of claim 13 to be unpatentable, the validity of a vast number of well-known diagnostic patents - including tests for prostate cancer and HIV - would be in question, because all such tests involve, literally or substantively, a similar assay-plus-correlation method. Boston Patent Law Association argued that the relation between elevated levels of homocysteine and vitamin B deficiency was not a law of nature or scientific principle because levels of homocysteine is associated with many diseases other than vitamin B deficiency.<sup>46</sup>

Franklin Pierce Law Center argued that the prohibition against patent claims directed to the so called laws of nature has to be discarded.<sup>47</sup> It submitted that the doctrine was an outcome of English Common law and does not merit protection under the US patent statute as the doctrine is relic, error prone, redundant and obsolete.

### *Neutral Arguments*

A few neutral Amici briefs were also filed. United States government argued that the co-relating step of claim 13 is invalid as it covers aspects that are not permitted by the statute i.e. the basic or fundamental relationship between homocysteine and vitamin deficiency.<sup>48</sup> Financial Services Industry argued that the development of financial services industry has been based on business method patents, which provides the required incentives and competitive advantage. Therefore, the decision in *Diehr* should be upheld to safeguard the interests of financial institutions.<sup>49</sup> Association of the Bar of the City of New York argued that the standards for determining whether a patent claim covers patentable subject matter as enunciated in *Diamond v. Diehr* should be reaffirmed by the Court.<sup>50</sup> IBM submitted that the Federal Circuit has construed the construction under *Diehr* very broadly since 1981 that non-technological methods have been granted patents by USPTO and that the court should limit patent grants to methods that have a technological component.<sup>51</sup>

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<sup>45</sup> Brief for Amici Curiae Perlegen Sciences, Inc. and Mohr, Davidow Ventures, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2006 WL 303908.

<sup>46</sup> Brief of Amicus Curiae Boston Patent Law Association, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2006 WL 303909.

<sup>47</sup> Brief Amicus Curiae Franklin Pierce Law Center , Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2006 WL 304571.

<sup>48</sup> Brief for the United States as Amicus Curiae, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3533248.

<sup>49</sup> Brief of Financial Services Industry Amici Curiae, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3543097.

<sup>50</sup> Amicus Curiae Brief of the Association of the Bar of the City of New York, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3597808.

<sup>51</sup> Brief of International Business Machines Corporation as Amicus Curiae, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3597815.

The arguments primarily revolved around whether the co-relation between homocysteine and cobalamine/folic acid was a scientific principle or natural law. The petitioner argued that it is a natural law or principle and the respondent argued that it is not. Most Amici in support of both parties submitted that granting or not granting a patent over the co-relation would have an impact on scientific progress, medical treatment and diagnosis. Such arguments would be moot in the light of Chakrabarty's case because the Supreme Court in that case held that such issues cannot be considered by the courts because they fall within the domain of Legislature and not courts. Amici that filed neutral arguments submitted that the jurisprudence relating to business methods or software that evolved based on Diehr should not be disturbed by the Laboratory Corp. case.

### C. Dismissal of the writ of certiorari

After hearing all the arguments, the US Supreme Court dismissed the writ of certiorari as improvidently granted<sup>52</sup>. By dismissing the writ, the Supreme Court upheld the decision of the Federal Circuit, which means that Claim 13 of the patent is valid and that Laboratory Corp. is liable for patent infringement. As the court did not decide the case, it did not change the existing principles relating to patentability. Three judges of the Supreme Court dissented the dismissal of the case by stating that the case is too important to be dismissed<sup>53</sup>. They observed that the procedural objection raised by the Respondent was tenuous and that it was necessary in furtherance of public interest to clarify the line between a patentable invention and a non-patentable natural principle. The judges also pointed out that the record was comprehensive enough to merit a decision.

## III. Conclusion

The perception of the extent of involvement of the scientific or natural principle in an invention generally determines the patentability of the invention. If the scientific or natural principle is being claimed as a patent, such an invention or discovery would not be eligible for patent protection. However, an invention would be eligible for patent protection if it is a practical application of a basic principle in science or nature. In other words, if a scientific or natural principle is practically applied in an invention, then it would be eligible for a patent. The test for determining whether what is claimed is a scientific principle or natural law or their practical application had not been clearly defined by the Supreme Court. Though the court in Chakrabarty's case held that an invention is considered to be non-natural, if it involves a hand of man, the test cannot be applied in all cases and is generally limited to biotechnology products. As the objective behind exclusion of scientific principles and natural laws from patentability is to prevent

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LABORATORY CORPORATION OF AMERICA HOLDINGS, dba LABCORP, PETITIONER v. METABOLITE LABORATORIES, INC., et al., No. 04-607 (June 22, 2006).

<sup>53</sup> JUSTICE BREYER, with whom JUSTICE STEVENS and JUSTICE SOUTER join, dissenting. LABORATORY CORPORATION OF AMERICA HOLDINGS, dba LABCORP, PETITIONER v. METABOLITE LABORATORIES, INC., et al., No. 04-607 (June 22, 2006).

their preemption from the general public, most decisions are made by checking if granting a patent over the invention would preempt the scientific principle or natural law from the public.

Most arguments made before the Supreme Court in the Laboratory Corp. case were based on the practical application or preemption of the natural co-relation between homocysteine and cobalamine or folic acid from the general public. While the petitioner and Amici on his behalf argued that the co-relation between homocysteine and Vitamin B is a natural relationship and therefore a law of nature making it ineligible for a patent grant, the respondent argued that the assaying step and co-relation is a practical application of a natural relationship and therefore not a law of nature [thus] making it patentable. It was also argued by the petitioner and Amici in his support that granting a patent on the "co-relation" would preempt the public from using the co-relation for developing new inventions based on it and for diagnostic purposes. The respondent and Amici in his support rebutted by stating that granting a patent would not preempt the "co-relation" from the public as it has many other uses apart from the one claimed in the patent.

Discovery of scientific principles or natural laws is as important as their application to specific inventions. In the present case, the inventor discovered the co-relation between homocysteine and folic acid/cobalamine and claimed a patent over a method of diagnosing the deficiency, which involves an "assaying step" and a "co-relating step". Among the two steps, the "assaying step", which includes the method of calculating levels of an amino acid (such as homocysteine) in the blood is well known in the prior art. However, the combination of the "assaying step" and the "co-relating step" was not known as the co-relation between homocysteine and folic acid/cobalamine remained undiscovered. The scientist in this case not only discovered an important relationship but also applied the relationship to a process of diagnosing a deficiency. Though one of the steps, i.e. the "assaying step", is well known, the process of diagnosing was not known. As per the decisions of the Supreme Court, a process as a whole would be patentable even if it involves a natural or scientific principle or if a step involved in it is well known. Applying this logic to the present case, though the "assaying step" is well known and the "co-relation between homocysteine and folic acid/cobalamine" is a natural relationship, their combination in process does not amount to a natural law or scientific principle but its application in a specific process and is therefore, patentable. Furthermore, the patent claim pre-empts only the application of natural relationship to process of diagnosing deficiency of Folic acid/Cobalamine and not the relationship itself. The Supreme Court did the right thing by dismissing the writ and therefore upholding the decision of the Federal Circuit, which gives rise to the aforementioned effect.

By indirectly upholding patentability of Claim 13, the Supreme Court has rightly given importance to discovery of natural laws or scientific principles and their specific application. While granting a patent over discovery of a generic scientific principle like law of gravity or upthrust would be counterproductive to the objectives of the patent system, grant of a patent over specific scientific or natural principles such as relation between amino acids or genes and disorders in human body like the one in the present

case would be beneficial to its ends. Granting patents over such relationships would encourage research in discovering such relationships and benefit the ends of patent law, which is to promote progress of science and technology. If patents are denied to such specific relationships, inventive activity promoted by patent law would be limited to their specific application without much focus on discovering unknown relationships. By holding Claim 13 patentable and infringed, the court in the Laboratory Corp. case has given the impetus for basic scientific discovery and related inventive activity. The decision in the case opens gates for rapid progress of biology by clarifying that both unknown natural relationships and their practical applications are patentable. Though the court has not laid down any principle, it has removed a certain amount of ambiguity relating to law of nature and scientific principle exceptions.