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# THE EXPANSION OF STATUTORY SUBJECT MATTER UNDER THE 1952 PATENT ACT<sup>+</sup>

### *Robert Greene Sterne and Lawrence B. Bugaisky*\*

## I. EXPANSION OF STATUTORY SUBJECT MATTER UNDER THE 1952 PATENT ACT

It is quite surprising that a mere four words were sufficient to establish a fundamental framework for defining the categories of patentable inventions. This framework has successfully stood for a period of more than 200 years. The 1793 Patent Act<sup>1</sup> defined the four classes of statutory subject matter as "art, machine, manufacture, or composition."<sup>2</sup> The 1952 Patent Act ("Patent Act" or "1952 Act")<sup>3</sup> replaced the term "art" with "process," resulting in the current language of 35 U.S.C. § 101.<sup>4</sup>

The legislative history of the Patent Act states that "art" as used in § 101: "is interpreted by the courts to be practically synonymous with

1. The Patent Act of 1793, ch. 11, § 1, 1 Stat. 318. The 1793 Act was the successor to the first United States Patent Act of 1790. 1 Stat. 109. There were subsequent patent statutes in 1836 (Act of July 4, 1836), 5 Stat. 117; 1870, 16 Stat. 198; and 1874, 18 Stat. 78.

2. These categories were maintained through the subsequent Patent Acts until 1952. 29 Stat. 692; 32 Stat. 1225; 45 Stat. 732; 46 Stat. 37; 53 Stat. 1212.

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<sup>&</sup>lt;sup>†</sup> This paper was originally presented at the Fifth Annual Richard C. Sughrue Symposium on Intellectual Property Law and Policy on March 10, 2003. A database search has not found any significant decisions concerning statutory subject matter that have been decided since the original presentation. An electronic version of the paper has been posted on the Sterne, Kessler, Goldstein & Fox, P.L.L.C., web site (www.skgf.com).

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<sup>3. 66</sup> Stat. 797 (Act of July 19, 1952).

<sup>4. 35</sup> U.S.C. § 101 (2002). "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 therefore, subject to the conditions and requirements of this title." *Id.* 

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process or method. The word 'process'<sup>5</sup> has been used to avoid the necessity of explanation that the word 'art' as used in this place means 'process or method.'"<sup>6</sup>

Despite the absence of any substantial change in the statutory language, there has been a substantial expansion of the subject matter being claimed in issued U.S. patents over the last 50 years. This expansion is the result of judicial interpretation of the essentially unchanged language of the Patent Act, and administrative guidelines from the United States Patent and Trademark Office.

The expansion of statutory subject matter appears to have been driven by two mutually reinforcing factors. The first one, of course, is the accelerating pace of invention as technology continues to rapidly advance. More importantly, however, is the fact that the 1952 Act did not include any express exclusionary limits on statutory subject matter.<sup>7</sup>

One of the landmark cases concerning statutory subject matter was the 1980 Supreme Court decision in *Diamond v. Chakrabarty*<sup>8</sup> that upheld the patentability of genetically engineered oil-eating bacteria. That decision resulted, at least in part, from the absence of express exclusionary language in the Patent Act. The Court noted that "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws be given wide scope."<sup>9</sup>

In *Chakrabarty*, the Court further stated that "Congress employed broad general language in drafting [the Patent Act] precisely because . . . inventions are often unforeseeable."<sup>10</sup> Referring to the legislative history, the Court suggested that statutory subject matter should include "anything under the sun that is made by man."<sup>11</sup> After *Chakrabarty*,

8. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980) (describing the subject matter at issue as a "genetically engineered bacterium capable of breaking down multiple components of crude oil. Because of this property . . . Chakrabarty's invention is believed to have significant value for the treatment of oil spills.")

<sup>5. 35</sup> U.S.C. § 100(b) (2002) further defines a process to mean "process, art or method."

<sup>6.</sup> S. Rep. No. 82-1979 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2398-99.

<sup>7.</sup> While 35 U.S.C. § 101 does not specifically exclude specific types of subject matter as being non-statutory, the courts have. For example, included in non-statutory subject matter are laws of nature, physical phenomena, a conceptual energy model and abstract ideas. *See In re* Bonczyk, No. 01-1061, 2001 U.S. App. LEXIS 9256 (Fed Cir. May 11, 2001); Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 66 (1972); Funk Bros. Seed. Co. v. Kalo Co., 333 U.S. 127, 130 (1948). Additional types of matter considered non-statutory by the courts include merely an idea, a principle in the abstract, an original cause, and a motive. *See* Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 507 (1874); LeRoy v. Tatham, 55 U.S. 156 (1853).

<sup>9.</sup> *Id* at 308.

<sup>10.</sup> *Id* at 316.

<sup>11.</sup> Id at 310 (quoting S. REP. NO. 82-1979 (1952), reprinted in 1952 U.S.C.C.A.N. 2394).

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reference to statutory subject matter and "anything under the sun" appeared frequently in decisions.<sup>12</sup> Thus, the absence of any express limitations on the four statutory categories has been the second basis for significant judicial expansion of allowable subject matter.

One year after *Chakrabarty*, the Supreme Court in *Diamond v*.  $Diehr^{13}$  considered a completely different technology: a "process" carried out using a computer with a stored program.<sup>14</sup> As in *Chakrabarty*, the Court stated that "we have more than once cautioned that 'courts should not read into the patent laws limitations and conditions which a legislature has not expressed."<sup>15</sup> As a result, the process was found to be within the bounds of allowable statutory subject matter.

The approach to patentable subject matter taken in the European Patent Convention contrasts starkly with that in the United States. The Convention<sup>16</sup> expressly excludes numerous categories of subject matter: (a) mere discoveries, scientific theories and mathematical models, (b) aesthetic creations, (c) schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers, (d) presentation of information, (e) methods of treatment of the human or animal body, and (f) plant or animal varieties or essentially biological processes for the production of plants or animals.<sup>17</sup> Needless to say, this results in a decreased diversity in the types of subject matter

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as invention which are susceptible of industrial application... European Patent Convention, Article 53 (b), Exceptions to Patentability. European patents shall not be granted in respect of: ... (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes to the products thereof.

Id. 17. Id.

<sup>12.</sup> See State St. Bank & Trust v. Signature Fin. Group, Inc., 149 F.3d 1368, 1372 (Fed. Cir. 1998); Ex parte Allen, 2 U.S.P.Q.2d 1425 (B.P.A.I. 1987).

<sup>13.</sup> Diamond v. Diehr, 450 U.S. 175 (1981).

<sup>14.</sup> Id.

<sup>15.</sup> Id. at 182 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).

<sup>16.</sup> European Patent Convention, Article 52 (1, 2 and 4). The Convention states:

Patentable Inventions.

<sup>(1)</sup> European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

<sup>(2)</sup> The following in particular shall not be regarded as inventions with the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creation; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information . . .

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found patentable compared to U.S. practice.<sup>18</sup>

Issues concerning statutory subject matter first arise during *ex parte* proceedings in the United States Patent and Trademark Office (PTO). If a claim is not rejected on grounds of unallowable statutory subject matter by an examiner, the claimed subject matter becomes allowable statutory subject matter by administrative default. In contrast, if the claim is rejected by the PTO and later considered on judicial review of the PTO rejection, additional statutory subject matter is in effect brought within the words of the Patent Act by judicial interpretation. Alternatively, it is possible that a claim that has been allowed by the PTO will be challenged after examination during infringement litigation on the grounds that it encompasses subject matter that is not within the language of the Patent Act.

Statutory subject matter rejections have been raised by examiners against many different kinds of inventions including, but not limited to: medical treatment claims,<sup>19</sup> printed matter,<sup>20</sup> computer software,<sup>21</sup> business methods,<sup>22</sup> kits,<sup>23</sup> genetically-altered microorganisms,<sup>24</sup> intermediary or transitory products in compositions,<sup>25</sup> and plant seeds.<sup>26</sup> Of course, this list is not all-inclusive. In some instances, the so-called non-statutory subject matter became patentable after further consideration of examiners' decisions by the courts or changes in the PTO rules.

The concept of statutory subject matter has sometimes become muddy because in a number of instances the PTO has rejected claims for lack of statutory matter, when in fact the rejection should have been based on other provisions of the Patent Act. These additional reasons for rejection include, but are not limited to, issues concerning

<sup>18.</sup> There is some commonality with regard to fundamental ideas, algorithms and other categories excluded from patenting in the United States as a result of judicial decisions. *See supra* note 8.

<sup>19.</sup> *Ex parte* Scherer, 103 U.S.P.Q. (BNA) 107 (B.P.A.I. 1954). While surgical techniques are considered patentable subject matter, Congress enacted 35 U.S.C. § 287(c) (2001) (110 Stat. 3009, September 30, 1996), providing remedies against medical practitioner and related health entities performing such an activity.

<sup>20.</sup> See In re Jones, 373 F.2d 1007 (C.C.P.A. 1967); In re Miller, 418 F.2d 1392, (C.C.P.A. 1969).

<sup>21.</sup> Gottschalk v. Benson, 409 U.S. 63 (1972).

<sup>22.</sup> State St. Bank, 149 F.3d at 1368.

<sup>23.</sup> In re Venezia, 530 F.2d 956 (C.C.P.A. 1976).

<sup>24.</sup> Diamond v. Chakrabarty, 447 U.S. 303 (1981).

<sup>25.</sup> In re Breslow, 616 F.2d 516 (C.C.P.A.1980).

<sup>26.</sup> Pioneer Hi-Bred. Int'l Inc. v. J.E.M. Agric. Supply, 200 F.3d 1374 (Fed. Cir. 2000).

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enablement, written description, novelty and obviousness.<sup>27</sup> Analytically, these additional requirements do not function as narrowing restrictions on the classes of statutory matter. Rather, the additional restrictions impose tests that the application must pass once it has passed through the initial door to patentability: meeting the statutory subject matter requirement.

This article is not intended to provide a complete review of all cases involving the expansion of statutory subject matter since enactment of the 1952 Act.<sup>28</sup> The attached table does, however, list a number of significant cases, and a few of these are briefly discussed below.

## II. ALGORITHMS, SOFTWARE AND COMPUTER-RELATED ISSUES

The law concerning the patentability of computer-related inventions and whether they are statutory matter has undergone a series of changes since the passage of the 1952 Act. While the Supreme Court has not expressly overruled its prior decisions, an observer can readily conclude that the Justices have changed the scope of patentable subject matter in this area. A series of decisions<sup>29</sup> has resulted in an evolution away from an apparent absolute bar on patenting anything relating in any way to an algorithm. This evolution now provides principles that allow patenting of such subject matter if there is a practical application for the algorithm or if it is associated with a tangible medium.

Algorithms *per se* have long been held not to be statutory subject matter and the 1972 Supreme Court decision in *Gottschalk v. Benson*<sup>30</sup> essentially precluded patent protection for software *per se*, on the grounds that software programs are essentially only a collection of algorithms. The Court, however, left the door open for the patenting of novel and non-obvious programming methods as well as software that was embodied in or used in connection with a mechanical device.<sup>31</sup>

One example of the patenting of software that was associated with a machine was the automatic record-keeping system that banks could use to provide bookkeeping services on their statements that was considered

<sup>27.</sup> These other provisions include 35 U.S.C.S. § 102 (2002); 35 U.S.C. §§ 103, 112 (2002).

<sup>28.</sup> Extensive detailed treatment of statutory subject matter can be found in several treatises, such as D.S. CHISUM, CHISUM ON PATENTS § 1.01 (2002); M.A. ADELMAN, PATENT LAW PERSPECTIVES § 1.01 (2d ed. 2002).

<sup>29.</sup> See Parker v. Flook, 437 U.S. 584 (1981); In re Alappat, 33 F.3d 1526 (Fed. Cir. 1994); State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998); Gottschalk v. Benson, 409 U.S. 63 (1972); Diamond v. Diehr, 450 U.S. 175 (1981).

<sup>30.</sup> Gottschalk, 409 U.S. at 72-73.

<sup>31.</sup> Id. at 73.

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in *In re Johnston.*<sup>32</sup> Those claims were allowed because they were drawn to a description of a machine that was controlled by an appropriately programmed digital computer rather than being drawn to the computer program itself.<sup>33</sup> Similarly, a method for curing rubber that used as one of its steps a mathematical formula and a programmed computer was found to be patentable subject matter in *Diamond v Diehr*,<sup>34</sup> where the Supreme Court affirmed the Court of Customs and Patent Appeals'<sup>35</sup> conclusion that patentability of the process should not be defeated merely because a mathematical formula was used.

In 1994, the Federal Circuit described the concept of statutory subject matter for computer-related inventions as follows:

[T]he proper inquiry in dealing with the so called mathematical subject matter exception to [patentability] is to see whether the claimed subject matter as a whole is a disembodied mathematical concept, whether categorized as a mathematical formula, mathematical equation, mathematical algorithm, or the like, which in essence represents nothing more than a 'law of nature,' 'natural phenomenon,' or 'abstract idea.' If so, Diehr precludes the patenting of that subject matter.

. . .

... This is not a disembodied mathematical concept which may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete, and tangible result.<sup>36</sup>

The evolving justification for allowing patents for device-connected software, while disallowing them for software *per se*, formed the basis for the appeal in *In re Beauregard*.<sup>37</sup> In that case, IBM challenged the PTO's rejection of an application to patent software in the form of a program stored on computer media.<sup>38</sup> IBM argued for an extension of the existing principles.<sup>39</sup> After IBM's brief was filed, the Commissioner of Patents decided to issue new examination guidelines for computer

<sup>32.</sup> In re Johnston, 502 F.2d 765 (C.C.P.A. 1974), rev'd on other grounds Dann v. Johnston, 425 U.S. 219 (1976).

<sup>33.</sup> Id. at 771.

<sup>34.</sup> Dier, 450 U.S. at 192-93.

<sup>35.</sup> The Court of Customs and Patent Appeals was the predecessor to the Circuit Court of Appeals for the Federal Circuit.

<sup>36.</sup> In re Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

<sup>37.</sup> In re Beauregard, 53 F.3d 1583 (Fed. Cir. 1995).

<sup>38.</sup> *Id*.

<sup>39.</sup> Id.

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software.<sup>40</sup> These new guidelines opened the existing doorway to patentability so wide that inventors can now, in effect, patent any computer software provided that it is embodied in a medium such as a diskette.<sup>41</sup> That change, for all practical purposes, reversed the result of the *Gottschalk* decision.

#### III. PRINTED MATTER ISSUES

Printed matter has historically not been considered statutory subject matter. The Court of Customs and Patent Appeals (CCPA), however, in 1967 drew a distinction between "printed matter," which has the primary purpose of conveying information to a reader, and "pattern areas" on a disc which actually functioned as a "structure."<sup>42</sup> The court further stated that it was "error to confuse the lines of a patent drawing . . . with functional elements of a mechanism which in use actuate other mechanisms."<sup>43</sup> Thus, while both algorithms *per se* and printed matter, when either was used in a framework associated with a physical structure, they were found to be patentable statutory subject matter.

#### IV. BUSINESS METHODS

A "business method," which in the past had been considered nonstatutory either because it was printed matter or software, has recently been found to be statutory subject matter in *State Street Bank*.<sup>44</sup> There, the Federal Circuit decided that determination of whether claims "are directed to subject matter within 35 U.S.C. § 101 should not turn on whether the claimed subject matter does 'business' instead of something else."<sup>45</sup>

## V. BIOTECHNOLOGY AND CHEMICAL RELATED ISSUES

The modern era of biotechnology patenting opened with the 1980 *Chakrabarty*<sup>46</sup> decision that genetically manipulated bacteria was

<sup>40.</sup> Examination Guidelines for Computer Related Inventions, 61 Fed. Reg. 7478, 7479 (1996).

<sup>41.</sup> Beauregard, 53 F.3d at 1584.

<sup>42.</sup> In re Jones, 373 F.2d 1007, 1012 (C.C.P.A. 1967) (stating that "a dark area on a light base can be an element of structure").

<sup>43.</sup> Id. at 1013.

<sup>44.</sup> State St. Bank & Trust v. Signature Fin. Group, 149 F.3d 1368 (Fed. Cir. 1998).

<sup>45.</sup> *Id.* at 1377.

<sup>46.</sup> See Diamond v. Chakrabarty, 447 U.S. 303 (1981).

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statutory subject matter. Subsequently, numerous biotechnology inventions, never previously deemed patentable, were granted patents.<sup>47</sup> As with other technologies, the patenting of biotechnology inventions has been facilitated by the Federal Circuit's narrow interpretation of potentially excludable matter.<sup>48</sup>

The patenting of multicellular organisms had been an issue for some time, when in 1987, the PTO position on this matter was clarified<sup>49</sup> in an Official Gazette Notice and in 1988 when the "Harvard Mouse" became the first patented mammal.<sup>50</sup> Today, patentable biotechnology includes genetically manipulated animals such as rats, pigs, sheep, and even genetically manipulated foods such as tomatoes, rice and corn.

In general, determination of whether something in the biotechnology area falls within the parameters of statutory subject matter has not required further major decisions by the courts, but simply application of precedential decisions such as *Chakrabarty*. One temporary exception to the trend of allowing patents under the Patent Act concerned multicellular plants which were initially considered to be non-allowable subject matter under § 101 because there were other statutes covering this intellectual property.<sup>51</sup> A 1985 PTO decision<sup>52</sup> and the 2000 Federal Circuit decision of *Pioneer Hi-Bred*<sup>53</sup> clarified the issue and established that multicellular plants are indeed patentable subject matter under § 101.<sup>54</sup>

The chemical area has also presented unique issues in terms of statutory subject matter. The CCPA decision of *In re Breslow*<sup>55</sup> addressed the issue of whether an intermediary or transitory product could be considered statutory subject matter. The Federal Circuit posed the question as "how long must a new and useful compound, which can

<sup>47.</sup> A detailed discussion of the patentability of biotechnology inventions has been published in IVER P. COOPER, BIOTECHNOLOGY AND THE LAW (West Group, 2001). *See also* KENNETH J. BURCHFIELD, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT (BNA Books, 1995).

<sup>48.</sup> See Arrhythmia Res. Tech. v. Corazonix Corp., 958 F.2d 1053, 1061 (Fed. Cir. 1992) (Rader, J., concurring).

<sup>49. &</sup>quot;The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms including animals, to be patentable subject matter within the scope of 35 U.S.C. Section 101." 1077 O.G. 24 (April 21, 1987). U.S. Patent No. 4,736,866 (Leder *et al.*) (issued April 12, 1988).

<sup>50.</sup> U.S. Patent No. 4,736,866 (Leder et al.) (issued April 12, 1988).

<sup>51.</sup> Plant Patent Act of 1930 (PPA), 46 Stat. 376; The Plant Variety Protection Act of 1970 § 42, 84 Stat. 1542, amended by 1994 Amendments, Publ. L. No. 103-349, § 3, 108 Stat. 3138, 7 U.S.C. § 2402(a) (2002)

<sup>52.</sup> Ex parte Hibbard, 227 U.S.P.Q. 443 (B.P.A.I. 1985).

<sup>53.</sup> Pioneer Hi-Bred. Inc. v. J.E.M. Agric. Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000)

<sup>54.</sup> Id.

<sup>55.</sup> In re Breslow, 616 F.2d 516 (C.C.P.A. 1980).

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be made at will for its intended purpose, . . . exist to be considered as a 'composition of matter' under 35 U.S.C. § 101?<sup>56</sup> The court disagreed with the PTO's attempt to "read into 35 U.S.C. § 101 a requirement that composition of matter must be stable.<sup>57</sup> This decision is consistent with decisions in other technology areas, where courts have broadly interpreted the Patent Act and refused to insert express limitations in considering what may potentially be statutory subject matter.

#### VI. THE FUTURE

The Patent Act has served admirably well in permitting the continued expansion of statutory subject matter over the last 50 years and will presumably continue to do so without the need for significant change in the future. The strength of the Patent Act has been its lack of specific exclusionary limitations, thereby permitting broad discretion in judicial interpretation. The existing language of the Patent Act and the history of judicial interpretation, as well as recent PTO administrative guidelines, should result in continued expansion in what will be deemed patentable subject matter. Based on this history, there appears to be no compelling reason why future patentable subject matter in any technology area cannot be addressed under the current statutory provision.

As new technologies emerge, the PTO and the courts will need to address each new subject matter with an open mind. The biggest problem in this regard, however, may be that new technologies can raise previously unencountered ethical, moral, economic and public policy issues that are analytically unrelated to a construction of the Patent Act but tend to "muddy" the analysis.<sup>58</sup> It is essentially impossible to anticipate specific issues in advance because an invention is frequently the creation of something previously unimaginable. Unimaginable things can create previously unimaginable issues for society.

New issues relating to potential statutory subject matter may overlap into the arena of what *should be* patented, rather than what is actually patentable under the Patent Act. In theory, such issues should not affect the patent examination process or a court's determination of what is statutory subject matter. Of course, the reality of the situation may ultimately be dictated by public policy concerns.

As new technologies arise, they will need to be addressed on an

<sup>56.</sup> *Id* at 519.

<sup>57.</sup> Id. at 521.

<sup>58.</sup> Such an example might arise if someone tried to patent a cloned human being.

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individual and innovative basis. For example, the PTO issued a patent to a surgical method, thereby placing methods of practicing medicine into the statutory category. Shortly thereafter, questions occurred from health practitioners to Congress concerning their ability to treat their patients without being sued for infringement. The easiest solution might have been for either the courts or Congress to exclude such "surgical methods" from the category of statutory subject matter. Instead, Congress provided a limited exemption from infringement liability to address the concerns of such health practitioners without changing the definition of patentable subject matter.

This congressional remedy was a new provision in the Patent Act<sup>59</sup> that permitted health practitioners and health care facilities to engage in "medical activity"<sup>60</sup> that infringed a patent without being sued for infringement.<sup>61</sup> Therefore, one need not necessarily restrict the categories of statutory matter in order to address possible complications arising from new technologies.

Another controversial statutory subject matter issue involves bioinformatics data that results from using sophisticated computer software to analyze biological research problems. In this scenario, an inventor might mine a database of information regarding proteins or nucleic acids and arrive at a "virtual structure"<sup>62</sup> having specific characteristics of interest. Under current interpretations of § 101, the raw database and the derived virtual structures cannot be patented, but if the virtual structure is actually converted into a physical structure, it becomes patentable subject matter. The problem with this current limitation is that much of the commercial investment, and resulting economic value, exists in the database itself and the virtual structures prior to any creation of the actual physical structure. One can argue that if patent protection were provided to the database itself, or the more limited area of the virtual structures, advances in technology would be facilitated, business would benefit and the valuable database itself would

Id.

<sup>59. 35</sup> U.S.C. § 287 (2001). The Act reads in part:

<sup>(</sup>c)(1)With respect to medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) or this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

<sup>60.</sup> The amendment defined "medical activity" narrowly to encompass only "performance of a medical or surgical procedure on a body." 35 U.S. \$ 287(c)(2)(A).

<sup>61.</sup> Of course, the practical result of this exemption to infringement may have been to significantly decrease the value of any patent issuing to such a surgical procedure.

<sup>62.</sup> In this context the "virtual structure" is a theoretical one that can be described in detail with respect to its structure and functional characteristics.

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be disseminated more quickly into the public domain, thus preventing unnecessary research duplication. <sup>63</sup> Others might argue that allowing patent protection of data itself or virtual inventions would transform the Patent Act into an Intellectual Property Protection Act with undesirable consequences. This debate is likely to become more intense as bioinformatics data becomes more prevalent in the research arena.

Another topic recently discussed in the scientific press involves man-made devices that can by themselves "invent" new devices. In one publication this concept was referred to as "genetic programming."<sup>64</sup> Is such a machine-created invention within the bounds of statutory subject matter? If so, who is the "inventor"? These and other questions wait for answers. Needless to say, however, it is certain that there will be many other such new technologies that will need to be addressed in the next decade as to whether they constitute statutory subject matter under the Patent Act.

<sup>63.</sup> Under current law the database and virtual structures could be protected as trade secrets, but that avenue does not provide the facilitation of improvements that the patent system does.

<sup>64.</sup> See John R. Koza, Martin A. Keane & Matthew J. Steeler, *Evolving Inventions*, SCIENTIFIC AMERICAN, Feb. 2003, at 52. At page 54 of this article, it is claimed that the authors have already filed for a patent on "a genetically evolved general-purpose controller that is superior to mathematically derived controllers commonly used in industry." *Id.* at 54. The authors apparently used the adjective "genetic" because the controller "evolved" from a machine process in a manner analogous to Darwin's concept of genetic evolution. *See id.* 

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# TABLE 1 - DECISIONS RELATING TO EXPANSION OFSTATUTORY SUBJECT MATTER

Decision	Comments	Invention
Ex parte Scherer,	Overruled examiner's	Medical treatment
103 U.S.P.Q. 107	decision preventing	claims.
(B.P.A.I. 1954).	patentability.	
In re Jones,	Distinguished printed	Code member with
373 F.2d 1007, 153	matter as a component	printed lines as part
U.S.P.Q. 77 (C.C.P.A.	of a machine.	of an optical reader
1967).		rotating disc.
Gottscchalk v. Benson,	Eliminated patent	Computer soft-ware
409 U.S. 63, 175	protection for computer	per se (program for
U.S.P.Q. 673 (1972).	software.	data processing).
In re Johnston,	The claimed machine	Record-keeping
502 F.2d 765, 183	was within the	machine system.
U.S.P.Q. (BNA) 172	technological art.	
(C.C.P.A. 1974).		
In re Venezia,	Group of interrelated	Kit with com-ponent
530 F.2d 956, 189	parts was a	parts, assembled in
U.S.P.Q. 149 (C.C.P.A.	manufacture.	the field.
1976).		
Parker v. Flook,	Process was not	Process using math-
437 U.S. 584, 198	patentable.	ematical formula
U.S.P.Q. (BNA) 193		and a programmed
(1981).		digital computer.
In re Kratz,	Alteration to products	Process-product
592 F.2d 1169, 201	from natural state –	imparting a straw-
U.S.P.Q. 71 (CCPA	manufacture.	berry flavor by add-
1979).		ing certain acids.
Diamond v. Chakrabarty,	Anything under the sun	Genetically-altered,
447 U.S. 303, 206	that is made by man.	live microorganism
U.S.P.Q. 193 (1980).		(oil eating bacteria).
In re Breslow,	Court rejected the idea	Intermediary or
616 F.2d 516, 205	that an unstable, inter-	transitory product
U.S.P.Q. 221 (C.C.P.A.	mediate or transitory	(composition).
1980).	product did not con-	
	stitute a composition	
	under §101.	

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Diamond v. Diehr,	Court confirmed the	Process (method of
450 U.S. 175, 209	patentability of an	operating a rubber
U.S.P.Q. (BNA) 1	industrial process that	molding press)
(1981).	included the use of a	including a math-
	mathematical formula	ematical formula
	and a computer as one	and a computer.
	of its steps.	
In re Gulack,	Printed matter issue.	Device with a series
703 F.2d 1381, 217		of numbers func-
U.S.P.Q. 401 (Fed.		tionally related to a
Cir.1983).		ring.
Ex parte Allen,	PTO extended protect-	Altered oysters (pro-
2 U.S.P.Q.2d 1425	ion to a multi-cellular	duct by process).
(B.P.A.I. 1987).	organism that is non-	
	naturally occurring.	
In re Lowry,	The invention was not	Data structure for
32 F.3d 1579, 32	printed matter.	storing, using and
U.S.P.Q.2d 1031 (Fed.		managing data in a
Cir 1994).		computer memory.
In re Beauregard,	Computer program em-	Tangible media with
53 F.3d 1583, 35	bodied in tangible med-	computer imp-
U.S.P.Q.2d 1383 (Fed.	ium such as a floppy	lemented method
Cir. 1985).	disc was patentable.	embedded within.
State St. Bank & Trust v.	Determination of	Data processing
Signature Fin. Group,	statutory subject matter	system for making
149 F.3d 1368, 47	should not turn on	necessary daily
U.S.P.Q. 1596 (Fed. Cir.	whether the invention	calculations.
1998).	does "business" rather	
	than something else.	

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#### EXPANSION OF STATUTORY SUBJECT MATTER