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Eric W. Gutttag

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# THE PATENTABILITY OF MICROORGANISMS: STATUTORY SUBJECT MATTER AND OTHER LIVING THINGS

Eric W. Guttag\*

## I. INTRODUCTION

For the past 200 years,<sup>1</sup> the federal patent laws have been used to encourage advances in scientific and technological areas. Pursuant to its constitutional authority "To Promote the Progress of Science and the Useful Arts,"<sup>2</sup> Congress has provided statutory protection for new and useful inventions.<sup>3</sup> Consistent with constitutional and congressional mandates, patent rights<sup>4</sup> have been granted for inventions which were diverse in both subject matter and complexity. For instance, the scope of patentable subject matter now extends to such highly sophisticated and revolutionary technologies as lasers, computers, and photocopiers.<sup>5</sup>

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\* Patent attorney with Procter-Gamble Corp., Cincinnati, Ohio; B.A., Carleton College, 1974; J.D., University of Richmond School of Law, 1977.

1. The first patent law was enacted shortly after the United States Constitution became effective. Act of April 10, 1790, ch. 7, 1 Stat. 109.

2. U.S. CONST. art. I, § 8, cl. 8. The stated constitutional objective of the patent laws is to encourage such "progress" by providing exclusive rights of limited duration to inventors in their creations in exchange for public disclosure of their ideas. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). However, the primary purpose of the patent system lies in advancement of the arts and sciences and not reward of the individual. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330-31 (1945). An inventor may find it more profitable not to disclose his idea, and thus protect it as a trade secret. For a discussion of the dual choice of the inventor, see *Kewanee Oil*, 416 U.S. 470, 487-88.

3. The present patent laws are codified in 35 U.S.C. § 1 *et seq.* (1970). Because Congress has exercised constitutional authority in this area, the states are preempted from granting rights equivalent to those created by the federal patent laws. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) (unpatentable pole lamp held not protectable under state unfair competition law); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964) (unpatentable reflector design held not protectable under state unfair competition law). In the unlikely event that Congress abolishes the federal patent laws, a state could still enact its own form of patent protection. *Cf. Kewanee Oil v. Bicron Corp.*, 416 U.S. 470 (1974) (state trade secret law not preempted by federal patent laws); *Goldstein v. California*, 412 U.S. 546 (1973) (state tape piracy statute not preempted by federal copyright laws) (state grants of patent protection in 18th century noted).

4. The holder of the patent is given the right for seventeen years from the date of issuance to prevent all others from making, using or selling the invention. 35 U.S.C. § 154 (1970).

5. Over 100,000 applications for patent protection are filed each year in the United States Patent and Trademark Office. Approximately 50,000 of these applications are issued each year as patents. *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). The patents issued (now over 4 million) are categorized into hundreds of classes and thousands of subclasses.

Due to the inherently fast moving characteristics of the field, it has been difficult for patent legislation to keep pace with technological change. There are recent indications that certain meritorious inventions may not be given a patent for their failure to fit into certain enumerated statutory classes of patentable subject matter. For example, the patentability of computer programs (software) was placed in doubt by the 1972 Supreme Court decision of *Gottschalk v. Benson*.<sup>6</sup> While the Court dealt with an extremely narrow issue, *Benson*, at least subtly, suggests that the patent laws may have been lost in the wake of technological progress.<sup>8</sup>

In addition to computer software, another area of very recent concern is the patentability of living organisms. The products of recombinant DNA research,<sup>9</sup> as well as other types of genetic engineering, have opened a new area of subject matter deserving patent law protection.<sup>10</sup> With this background, one court has attempted to resolve the question of microorganism patentability. The Court of Customs and Patent Appeals (CCPA) held in the case of *In re Bergy*<sup>11</sup> that a biologically pure culture of a microorganism was patentable subject matter. In the later and more extraordinary case of *In re Chakrabarty*,<sup>12</sup> the CCPA ruled that a novel, man-made, and

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6. 409 U.S. 63 (1972).

7. In *Benson*, claims to a method of converting binary-coded decimal numbers to pure binary numbers were held unpatentable as not defining a "process." Further doubt has been created by the recent decision of *Parker v. Flook*, 98 S.Ct. 2522 (1978), where a method for updating alarm limits in a catalytic conversion process was held unpatentable under 35 U.S.C. § 101 (1952). See note 26 *infra* for a further discussion of the *Benson* and *Flook* decisions.

The fact that a judicial body in 1948 is forced to use the same language as that found in the decisions of Baron Alderson, Lord Chief Justice Eyre, or Lord Mansfield with regard to the patentability of certain scientific claims, is certainly a vivid commentary upon the continuous and widening gap between the world of technological advance and the world of law.

8. Inlow, *That Non-Patentable Law of Nature*, 30 J. PAT. OFF. Soc'y 487, 488 (1948) (commenting on *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

9. DNA (deoxyribonucleic acid) is the basic genetic material of all living organisms. By utilizing certain special enzymes, man has been able to "cut and paste" this genetic material to form new genetic combinations, hence the term "recombinant." VAN NOSTRAND'S SCIENTIFIC ENCYCLOPEDIA 1894-96 (5th ed. 1976).

10. Another technique which has created some controversy is the cloning of parent organisms to produce offspring with identical genetic structures. Presently, clones of plants and certain lower forms of mammals have been created. I. Kayton, *Living Microorganisms*, ADVANCED U.S. PATENT PRACTICE 2, 12 (1978) [hereinafter cited as Kayton].

11. 563 F.2d 1031 (C.C.P.A. 1977).

12. 571 F.2d 40 (C.C.P.A. 1978).

genetically engineered species of microorganism was patentable.

*Bergy* and *Chakrabarty* are primarily concerned with the patentability of microorganisms, thus leaving two important issues open. The first narrower question is the extent to which living subject matter other than microorganisms are patentable. The second broader question asks what is an outer limit to patentable subject matter. In an attempt to answer these questions, the first part of this article will deal generally with patentable subject matter requirements, particularly in relation to microorganisms. The second part of this article will analyze the CCPA decisions of *Bergy* and *Chakrabarty* in order to ascertain the underlying principles relating to microorganisms as patentable subject matter. Finally, an attempt will be made to resolve these two questions regarding patentable subject matter and recent case law as discussed herein.

## II. THE STATUTORY CLASSES OF PATENTABLE SUBJECT MATTER

Section 101 of the patent statutes enumerates four classes of statutory subject matter.<sup>13</sup> The four categories are processes,<sup>14</sup> machines,<sup>15</sup> manufactures,<sup>16</sup> and compositions of matter.<sup>17</sup> To be enti-

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13. See 35 U.S.C. § 101 (1952), which also includes "improvements" of the four categories. The statutory classes have varied only slightly prior to the present statutes. See, e.g., Act of April 10, 1790, ch. 7, § 4, 1 Stat. 109 (art, manufacture, engine, machine, or device or improvement thereof); Act of February 21, 1793, ch. 11 § 1, 1 Stat. 318 (art, machine, manufacture, or composition of matter or improvement thereof). For a concise historical development of the statutory classes see *In re Chatfield*, 545 F.2d 152, 159 (C.C.P.A. 1976) (dissenting opinion), cert. denied, 54 L. Ed. 2d 155 (1977). For the purposes of this article, the phrases "patentable subject matter" and "statutory subject matter" are interchangeable.

14. "A process is a mode of treatment of certain materials to produce a given result. It is an act, or series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Cochrane v. Deener*, 94 U.S. 780, 788 (1876). Under the present statutes, the term "process" is equivalent to the words "process, art or method" and includes a "new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (1952). Prior to the present statutes, it was questionable whether a "new use" was patentable. E.g., *In re Thuau*, 135 F.2d 344, 347 (C.C.P.A. 1943) (new use of old compound unpatentable); *Old Town Ribbon & Carbon Co. v. Columbia Ribbon & Carbon Mfg. Co.*, 159 F.2d 379, 382 (2d Cir. 1947) (new use of old manufacture unpatentable). Even under the present statutes, a "new use" is patentable only as a "method" or "process." *In re Hack*, 245 F.2d 246, 248 (C.C.P.A. 1957) (new use claim to old composition unpatentable where not in "process" or "method" form). See also *Ex parte Müller*, 81 U.S.P.Q. (BNA) 261 (Pat. Off. Bd. App. 1947) (insecticide DDT claimed as "method for killing insects").

15. "The term machine includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." *Corning v. Burden*, 55 U.S. (15 How.) 503, 505-06 (1853). See also *Riter-Conley Mfg. Co. v. Aiken*.

tled to patent protection, a new and useful invention<sup>18</sup> must fall within at least one of these statutory classes.<sup>19</sup>

The courts have also enumerated a number of categories not entitled to patent protection by case law. For instance, an abstract principle, idea or law of nature has been repeatedly considered unpatentable.<sup>20</sup> Methods of doing business,<sup>21</sup> mental steps,<sup>22</sup> printed

203 F. 699, 702 (3rd Cir. 1913), ("machine" associated with something having operative motion or mobility), *cert. denied*, 229 U.S. 617 (1913). The words "apparatus" or "device" are also used and are equivalent to or encompassed by the term "machine." See J LANDIS, *MECHANICS OF PATENT CLAIM DRAFTING* §§ 11-12, at 17-20 (1st ed. 1974) [hereinafter cited as Landis]. See also *In re Chatfield*, 545 F.2d 152, 160 (C.C.P.A. 1976) (dissenting opinion) ("machine" and "apparatus" interchangeable), *cert. denied*, 54 L.Ed.2d 155 (1977).

16. "The term 'manufacture,' as used in the patent law, has a very comprehensive sense, embracing whatever is made by the art or industry of man, not being a machine, a composition of matter, or a design." *Johnson v. Johnston*, 60 F. 618, 620 (C.C.W.D. Pa. 1894). *But see* notes 53-61 *infra* and accompanying text which indicate that the definition of "manufacture" may not be so broad. As the above definition implies, the term "manufacture" is a catch-all category which encompasses a number of diverse, man-made products. See, e.g., *Park-In Theatres, Inc. v. Rogers*, 130 F.2d 745 (9th Cir. 1942) (drive-in theatre); *In re Venezia*, 530 F.2d 956 (C.C.P.A. 1976) (unassembled kit of interrelated parts).

17. The term "composition of matter" includes "all compositions of two or more substances and includes all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957) (citing *WALKER ON PATENTS*), *aff'd per curiam*, 252 F.2d 861 (D.C. Cir. 1958). See also LANDIS, *supra* note 15, § 46, at 119-20. The term usually refers to a product distinguished by its chemical nature as opposed to its physical shape or form. *Id.*

18. The word "invention" is a very ambivalent term in the patent law. It can be used to describe the entirety of the inventor's creation. See 35 U.S.C. § 112, par. 2 (1970). It has also been used to define the "patentable novelty" of the inventor's creation, i.e. that part which is a significant technological advance. See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948), which is discussed further at notes 72-80, *infra*, and accompanying text.

19. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974). A particular invention will frequently be covered by more than one class. See *In re Bergy*, 563 F.2d 1031, 1038 (C.C.P.A. 1977) (bacteria either a "manufacture" or "composition of matter"); *In re Jones*, 373 F.2d 1007, 1013 (C.C.P.A. 1967) (code disc for encoder either a "manufacture" or subcombination of a "machine").

20. E.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852). While certain countries such as the Soviet Union have granted protection for the bare discovery of a "law of nature" or the like, the United States patent statutes have been construed to cover only practical applications of such "laws." See, e.g., *Funk Bros.*, *supra* at 130; *Mackay Radio & Tel. Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939). See generally *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-20 (1853), where Samuel Morse, inventor of the telegraph, unsuccessfully attempted to claim "electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances. . ." as patentable.

21. *In re Chatfield*, 545 F.2d 152, 157 (C.C.P.A. 1976), *cert. denied*, 434 US 875 (1977)

matter,<sup>23</sup> and mathematical formulas or algorithms<sup>24</sup> have also been deemed outside the ambit of the patent laws. Although not always explicit on the issue, the courts imply that this excluded subject matter does not fall into any of the four statutory categories.<sup>25</sup>

In the case of microorganisms, it is conceivable that such subject

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(dictum), citing *In re Wait*, 73 F.2d 982 (C.C.P.A. 1934). In *Wait*, claims to a process for selling stocks, commodities and the like were apparently held invalid for want of novelty. After a careful reading, *Wait* does not necessarily support the dictum postulated in *Chatfield*. See *Wait*, *supra* at 983. See also *Hotel Security Checking Co. v. Lorraine Co.*, 160 F. 467, 472 (2d Cir. 1908), where the Court found it unnecessary to decide whether a new and useful system of cash registering and account-checking would be an "art" (process) within the meaning of the patent statutes.

22. *In re Benson*, 441 F.2d 682 (C.C.P.A. 1971), *rev'd sub nom.*, *Gottschalk v. Benson*, 409 U.S. 63 (1972) (method of converting from binary coded decimal numbers to pure binary numbers not "mental steps"). See *In re Bernhardt*, 417 F.2d 1395 (C.C.P.A. 1969) (method of portraying a three-dimensional object in two dimensions using a computer not "mental steps"); *In re Shao Wen Yuan*, 188 F.2d 377, 380 (C.C.P.A. 1951) (method of determining desired characteristics of airfoil profile unpatentable "mental steps"). The "mental steps" doctrine formed the first hurdle to the patentability of computer programs. *In re Abrams*, 188 F.2d 165, 168 (C.C.P.A. 1951) (method for detecting petroliferous deposits unpatentable "mental steps"). See also LANDIS, *supra* note 17, § 41, at 88-98, for an excellent discussion of the "mental steps" doctrine with respect to computer programs.

23. *Latz v. Reliance Graphic Corp.*, 98 F.2d 679 (2d Cir. 1938), *cert. denied*, 305 U.S. 648 (1938) (communication sheet not a "manufacture"); *In re Sterling*, 70 F.2d 910 (C.C.P.A. 1934) (bank checks and stubs thereof non-patentable subject matter); *In re Russell*, 48 F.2d 668 (C.C.P.A. 1931) (novel arrangement of names in directories and dictionaries non-patentable subject matter). However, "printed matter" is non-statutory only if the primary purpose is to convey intelligence to the reader. *In re Jones*, 373 F.2d 1007, 1012-13 (C.C.P.A. 1967) (patterns on code disc defined physical structure unrelated to any intelligence conveying function). See also *In re Miller*, 418 F.2d 1392, 1396 (C.C.P.A. 1969), where the CCPA held that volumetric indicia marked on a measuring cup should be given weight in determining patentability.

24. *Gottschalk v. Benson*, 409 U.S. 63 (1972). The Supreme Court considered mathematical formulas and algorithms analogous to unpatentable abstract ideas. See *id.* at 71. The inarticulate and frequently ambiguous language of *Benson* has caused considerable confusion in the CCPA. See *In re Johnston*, 502 F.2d 765 (C.C.P.A. 1974), *rev'd sub nom.*, *Dann v. Johnston*, 425 U.S. 219 (1976), where Judge Rich poignantly said: "I am probably as much-if not more-confused by the wording of the *Benson* opinion as many others." 502 F.2d at 773 (dissenting opinion). The CCPA's valiant effort to differentiate between patentable and non-patentable subject matter in view of *Benson* has not always been successful. Compare *In re Flook*, 559 F.2d 21 (C.C.P.A. 1977) (method of updating alarm limits of a process variable in a catalytic hydrocarbon conversion process held patentable subject matter), with *In re de Castelet*, 562 F.2d 1236 (C.C.P.A. 1977) (method for generating curves held unpatentable subject matter). The Supreme Court has recently reversed the CCPA in *Flook* with potentially adverse implications for other areas of patent law besides computer programs. *Parker v. Flook*, 46 U.S.L.W. 4791 (U.S. June 22, 1978).

25. See *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972); *Latz v. Reliance Graphic Corp.*, 98 F.2d 679, 680 (2d Cir. 1938), *cert. denied*, 305 U.S. 648 (1938).

matter could be considered patentable either as a "manufacture," or as a "composition of matter." This article now proceeds to a historical development of these two non-patentable categories by an examination of relevant case law.

### A. *Product of Nature*

The doctrine that a "product of nature"<sup>27</sup> cannot be patented has been frequently stated by various courts. While certain decisions have professed to rely on this doctrine, a careful consideration of the facts involved in the cases suggests that the basis for the holdings lies elsewhere.<sup>28</sup> For example, the two Supreme Court decisions of *American Wood-Paper Co. v. Fibre Disintegrating Co. (The Wood Paper Patent)*<sup>29</sup> and *Cochrane v. Badische Anilin & Soda Fabrik*,<sup>30</sup> which have been cited for the "product of nature" doctrine,<sup>31</sup> were actually attempts to patent old compounds.<sup>32</sup> The few cases that are clearly premised on the doctrine imply that a "product of nature" is non-statutory subject matter.<sup>33</sup>

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26. *In re Bergy*, 563 F.2d 1031, 1038 (C.C.P.A. 1977).

27. A "product of nature" is defined in this article as a naturally occurring element, composition of matter or substance that can be found in and extracted from minerals or living organisms. See Note, *Patent Law—Patentability as Affected by the Law of Nature Rules—The Kalo Doctrine*, 47 Mich. L. Rev. 391, 395 (1949) ("product of nature" one occurring on earth in form not changed by human act).

28. See *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931) (ductile uranium unpatentable), and *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931) (ductile vanadium unpatentable), where it appears that the pure elements were known or isolated prior to the applications for patent. See also *Patent Law*, supra note 27, at 396.

29. 90 U.S. (23 Wall.) 566 (1874).

30. 111 U.S. 293 (1884).

31. See *Merck & Co. v. Olin Mathieson Chem. Corp.*, 152 F. Supp. 690, 698 (W.D. Va. 1957), *rev'd*, 253 F.2d 156 (4th Cir. 1958).

32. In the *Wood Paper Patent* case, the patent was directed to a purer cellulose pulp suitable for manufacturing paper. The Supreme Court held the patent invalid in view of the fact that cellulose pulp suitable for manufacturing paper was used long before the patent in suit was applied for. 90 U.S. at 593-94. In the *Cochrane* case, the patent was directed to "artificially produced" alizarine. The Supreme Court correctly held that alizarine is alizarine whether produced artificially as in the patent in suit or by previously known extraction from the madder root. 111 U.S. at 311. See also *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938) ("artificial" ultramarine unpatentable).

33. See *General Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642-43 (3rd Cir. 1928), *cert. denied*, 278 U.S. 656 (1928) (pure tungsten unpatentable); *Ex parte Reed*, 135 U.S.P.Q. 34 (Pat. Off. Bd. App. 1961), *petition for reconsideration granted*, 135 U.S.P.Q. 105 (Pat. Off. Bd. App. 1961) (naturally occurring alpha-lipoic acid extracted from liver unpatentable); *Ex parte Berkmann*, 90 U.S.P.Q. 398 (Pat. Off. Bd. App. 1950) (physiologically active material derived from plants unpatentable); *Ex parte Snell*, 86 U.S.P.Q. 496 (Pat. Off. Bd. App. 1950)

A major difficulty for the courts has not been in stating the doctrine, but rather in determining whether there is such a doctrine and how to apply it. In *General Electric Co. v. De Forest Radio Co.*,<sup>34</sup> the inventor had patented "substantially pure tungsten having ductility and high tensile strength." Prior to that time, the element tungsten had not been produced in pure form, but rather existed in nature as an oxide. The court held the patent of the substantially pure tungsten to be invalid as a "product of nature." The court reasoned that, while the inventor had discovered the natural qualities of pure tungsten, he did not, in fact, create pure tungsten.<sup>35</sup>

In contrast to the *General Electric* case, other courts seem to take the position that there is no "product of nature" doctrine. In *Parke-Davis & Co. v. H. K. Wolford Co.*,<sup>36</sup> the inventor had patented adrenalin extracted from the glands of animals. Rejecting the contention that the extract was not a new "composition of matter," Judge Learned Hand held the claims to the extract valid on two grounds. First, he noted that others had believed that adrenalin was a salt, whereas the inventor's extract was in the form of a base, "a distinction not in degree, but in kind."<sup>37</sup> Second, Judge Hand stated that "even if it were merely an extracted product without change, there is no rule that such products are not patentable."<sup>38</sup> According to Judge Hand in *Parke-Davis*, whether or not adrenalin qualified as a "product of nature" was irrelevant to its patentability.

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(vitamin B-6 produced artificially unpatentable when shown to be naturally occurring substance). See also MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (55th Rev. 1978).

Although not expressed, the argument appears to be that a "product of nature" by definition is not man-made, and is therefore not within the enumerated statutory classes which protect only man-made creations. See *General Elec.*, *supra*. Another basis for the "product of nature" doctrine may be that the naturally occurring substance is not "new" within the meaning of the patent statutes. See *Merck & Co. v. Olin Mathieson Chem. Corp.*, 152 F. Supp. 690, 699-700 (W.D. Va. 1957), *rev'd*, 253 F.2d 156 (4th Cir. 1958).

34. 28 F.2d 641 (3rd Cir. 1928), *cert. denied*, 278 U.S. 656 (1928).

35. *Id.* at 643. While admittedly the inventor did not create the element tungsten, neither did nature create "pure" tungsten in that it was producible only by the inventor's process. Therefore, it is difficult to understand why "pure" tungsten could not be patented as a new "manufacture." See *Patent Law*, *supra* note 27 at 395.

36. 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

37. 189 F. at 103. The "distinction in kind rather than degree" phraseology has apparently been adopted by later courts as the test for separating patentable from unpatentable "products of nature." See cases cited in notes 46-47, *infra*.

38. 189 F. at 103. In Judge Hand's view, the extract was "a new thing commercially and therapeutically." *Id.*



Another decision which apparently rejected the "product of nature" doctrine is *Merck & Co. v. Olin Mathieson Chemical Corp.*<sup>39</sup> In *Olin Mathieson*, the inventors claimed a patent for vitamin B-12 active compositions which had been extracted from the fermentation products of a certain strain of fungi. The District Court held the claims to be invalid.<sup>40</sup> Although a number of grounds were presented for the invalidity of the claims,<sup>41</sup> the Court of Appeals found the primary basis for the conclusion of the District Court to be that the claims were directed to a "product of nature." In reversing the District Court, the Court of Appeals held that the activated B-12 compositions were new and useful "compositions of matter." At the same time, the Court of Appeals indicated that it was not impressed by the "product of nature" doctrine: "There is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability."<sup>42</sup>

Rather than either totally accepting or rejecting the "product of nature" doctrine, some courts have attempted to establish a distinction based on purification of the naturally occurring material.<sup>43</sup>

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39. 152 F. Supp. 690 (W.D. Va. 1957), *rev'g*, 253 F.2d 156 (4th Cir. 1958).

40. In holding the vitamin B-12 active compositions unpatentable "products of nature," the District Court found the compositions to "differ merely in degree, and not in kind" from naturally occurring materials. 152 F. Supp. at 699.

41. The District Court further held the compositions to be invalid, as lacking "invention" in the "patentable novelty" sense. 152 F. Supp. at 700.

42. 253 F.2d at 161. The Court of Appeals found the "product of nature" doctrine separable into two distinct doctrines. The first doctrine was that an old product was unpatentable even though derivable from a new source by a new process. Because the active compositions did not exist prior to the patent in suit, the first doctrine did not apply. The second doctrine was that a purified product did not represent a patentable advance if it differed merely in degree and not in kind. Because only the compositions of the patent in suit contained the therapeutically and commercially desired activity, the second doctrine was also inapplicable. *See id.* at 162-64. For other cases which apparently reject the "product of nature" doctrine, *see*, *Chas. Pfizer & Co. v. Barry-Martin Pharmaceuticals, Inc.*, 241 F. Supp. 191, 194 (S.D. Fla. 1965) (tetracycline held patentable although occurring naturally in trace amounts in Aureomycin); *Sterling Drug, Inc. v. Watson*, 135 F. Supp. 173, 176 (D.D.C. 1955) (1-arterenol separated from racemic mixture of arterenol found in glands of human body held patentable).

43. *See generally*, 20 GEO. WASH. L. REV. 232 (1951). An analogous line of cases involves the purification of non-naturally occurring materials. *In re Williams*, 171 F.2d 319 (C.C.P.A. 1948) (substantially pure laero rotary form of compound separated from racemic mixture held patentable); *In re Fink*, 62 F.2d 103 (C.C.P.A. 1932) (substantially oxygen free composite metal held unpatentable); *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 705 (7th Cir. 1910), *cert. denied*, 220 U.S. 622 (1911) (purified aspirin held patentable).

Mere purification of the naturally occurring material has been held insufficient to make the unpatentable product patentable.<sup>44</sup> However, purification which resulted in a difference of "kind rather than degree" has been held to be a patentable change.<sup>45</sup> In practice, the inventor is required to show that the purification of the naturally occurring product results in the extraction of a previously unknown substance,<sup>46</sup> or a known substance which has unexpected properties.<sup>47</sup>

The effort to rationalize the "product of nature" doctrine on the basis of degree of purification of the naturally occurring substance raises two interesting points with respect to the question of what constitutes patentable subject matter. First, some of the decisions cannot be easily distinguished simply on the basis of the degree of purity of the naturally occurring substance. Why extracted adrenalin is patentable while substantially pure tungsten is not is a question which the courts have failed to answer.<sup>48</sup> Secondly, the purified "product of nature" cases seem to indicate a general dissatisfaction with "product of nature" doctrine. It is clear that the courts did not regard the purification of the naturally occurring substance as merely a purified "product of nature", but rather as a new "composition of matter."<sup>49</sup> Indeed, the question usually raised was

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44. *In re King*, 107 F.2d 618 (C.C.P.A. 1939) (purified vitamin C held unpatentable); *In re Macallum*, 102 F.2d 614 (C.C.P.A. 1939) (purified composition of solid phosphate of calcium and hormone of duodenal mucosa held unpatentable); *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938) (artificially produced ultramarine having "non-floatable impurities" held unpatentable); *In re Ridgway*, 76 F.2d 602 (C.C.P.A. 1935) (purified alpha alumina held unpatentable).

45. *In re Doyle*, 327 F.2d 513 (C.C.P.A. 1964) (6-amino penicillanic acid extracted from penicillin producing moulds held patentable); *Ex parte Parke*, 64 U.S.P.Q. 335 (Pat. Off. Bd. App. 1944) (purified crystalline sodium d-panto-thenate held patentable); *Cf.*, *In re Williams*, 171 F.2d 319 (C.C.P.A. 1948) (substantially pure laero rotary form of compound held patentable).

46. *Cf.*, *In re Williams*, 171 F.2d 319 (C.C.P.A. 1948) (no showing that compound was known to be racemic).

47. *In re Doyle*, 327 F.2d 513 (C.C.P.A. 1964) (purified 6-amino penicillic acid shown to produce greater quantities of pure antibiotic); *cf.* *Kuehmsted v. Farbenfabriken of Elberfield Co.*, 179 F. 701, 705 (7th Cir. 1910) (purified aspirin therapeutically different from unpurified aspirin); *Ex parte Parke*, 64 U.S.P.Q. 335 (Pat. Off. Bd. App. 1944) (purified crystalline sodium d-pantothenate different in form and physical properties).

48. See note 37 *supra*.

49. See, e.g., *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (purified PGE<sub>2</sub> and PGE<sub>3</sub>, "new" within meaning of Section 101); *Merck & Co. v. Chase Chem Co.*, 273 F. Supp. 68, 83 (D. N.J. 1967) (later case in different circuit holding vitamin B-12 active compositions "new" compositions of matter). See also, *Ex parte Bergy*, 197 U.S.P.Q. 78, 82 (Pat. Off. Bd. App. 1976) (dissenting opinion):

whether this new "composition of matter" represented a patentable advance over the naturally occurring substance.<sup>50</sup>

In the midst of the purified "product of nature" cases is another line of cases which suggests that there may be an intermediate, unpatentable category between "products of nature" and the statutory classifications of patentable subject matter. The principle case in this area is *American Fruit Growers, Inc. v. Brogdex Co.*<sup>51</sup> In *American Fruit*, the inventor claimed that citrus fruit in which the rind had been impregnated with borax was a "manufacture." By so impregnating the rind, the fruit became resistant to blue mold decay. The Court of Appeals held that the complete article of the fruit and borax was patentable as it was "not found in nature" and was "thus an article of manufacture."<sup>52</sup>

The Supreme Court reversed, however, holding that the borax-impregnated fruit was not a "manufacture" within the meaning of the patent statutes. First, the Supreme Court defined patentable "manufactures" as, ". . . articles [produced] for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand-labor or by machinery.' Also 'anything made for use from raw or prepared materi-

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The expression "product of nature" does not appear in Section 101 and, as such, a material should not be excluded on that basis alone, as being non-statutory. Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

50. See *In re Bergstrom*, 427 F.2d 1394, 1402 (C.C.P.A. 1970) (whether pure compounds have the same usefulness or properties as impure compounds is a question of obviousness). Mere novelty of the invention is not enough for patent protection. It has long been a judge-made requirement that there be some sort of "patentable advance." See, e.g., *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1850) (more ingenuity and skill than an ordinary mechanic acquainted with business). See also *Cuno Eng'r Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941) ("flash of creative genius" rather than mere skill of the calling). Because of the diverse definitions of "patentable advance" by various courts, Congress attempted to uniformize the standard, now codified in 35 U.S.C. § 103, as "obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains." See *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (codification of precedents involving *Hotchkiss* standard). However, the attempt at uniformity has not been entirely successful. See *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 281-82 (1976), which suggests that a different standard be applied to "combination patents" (whatever that means).

51. 283 U.S. 1 (1931).

52. 35 F.2d at 108. The Court of Appeals also upheld the validity of the claims to the process for impregnating the fruit.

als.'"<sup>53</sup> The Supreme Court then applied its definition to the impregnated fruit:

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.<sup>54</sup>

In conclusion, the Supreme Court cited the tariff importation cases of *Hartranft v. Wiegmann*<sup>55</sup> and *Anheuser-Busch Brewing Ass'n v. United States*<sup>56</sup> for further support of its narrow definition of "manufacture" under the patent statutes.<sup>57</sup>

In view of the definition of "manufacture" selected by the Supreme Court in *American Fruit*, it seems difficult to understand why an impregnated fruit rind is not a "manufacture" within the meaning of the patent statutes. One commentator has attempted to rationalize the *American Fruit* decision on the basis that the effect of the borax coating was to create a property which was independent of the inherent qualities of the fruit.<sup>58</sup> However, the dictionary definition of "manufacture" utilized by the Supreme Court in *American Fruit* encompasses a "new combination" of existing materials. It would seem, then, that a fruit, the rind of which was impregnated with borax, would be a "new combination" of both the fruit and the borax. Yet, the Supreme Court in *American Fruit* appears to ignore arbitrarily the last part of its dictionary definition of "manufacture."<sup>59</sup>

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53. 283 U.S. at 11.

54. *Id.* at 11-12.

55. 121 U.S. 609 (1887).

56. 207 U.S. 556 (1908).

57. In *Hartranft*, the Supreme Court held that ground shells and shells etched by acid were not "manufactures of shells" within the meaning of the Act of March 2, 1861, ch. 68, § 22, 12 Stat. 192. In *Anheuser-Busch*, the Supreme Court held that specially treated corks were not "manufactures" within the meaning of the Act of October 1, 1890, ch. 1244, 26 Stat. 567. As to how the purposes of the tariff laws and the patent laws coincide so that definitions of the former can be used for the latter is unclear. Cf. *Microbiological Plant Patents*, 10 *IDEA* 87, 91 (1966).

58. Kayton, *supra* note 10, at 8 (necessary to render *American Fruit* consistent).

59. Because the Supreme Court had better grounds for its holding, the distorted definition

Application of the "new form, quality or property" test of *American Fruit* by the courts and the United States Patent and Trademark Office has not been an easy matter.<sup>60</sup> Most of the decisions indicate that articles which are the result of mechanical treatment will be excluded by the test,<sup>61</sup> while articles which are the product of chemical combination, treatment or reaction will not.<sup>62</sup> However, other cases seem to indicate a general lack of understanding of the *American Fruit* test.<sup>63</sup> A liberal application of the *American Fruit* test might also make it difficult to justify those cases holding purified "products of nature" as patentable subject matter.<sup>64</sup> However, these cases appear to have totally ignored *American Fruit*, as well as its definition of "manufacture."<sup>65</sup>

### B. *Living Subject Matter*

There is nothing in the patent statutes expressly prohibiting the patenting of living organisms. Processes employing living subject matter in the form of bacteria<sup>66</sup> or other organisms<sup>67</sup> have been re-

of "manufacture" is particularly regrettable. The Supreme Court also invalidated the process claims for impregnating the fruit, but on the ground that it was not novel because boric acid had been previously applied to various articles of food, including fruit. Thus, it seems logical that a borax impregnated fruit could similarly have been held invalid. *See* 47 Mich. L. Rev. 391, 396 n.28 (1949).

60. Some tribunals have apparently been leery of basing their holding of invalidity solely on the rationale of *American Fruit*. *See In re McKee*, 75 F.2d 636 (C.C.P.A. 1935) (application disclosing "frozen sliced meat" also held to lack "invention" over cited references); *Ex parte Grayson*, 51 U.S.P.Q. 413 (Pat. Off. Bd. App. 1941) (deveined shrimp also held to lack "invention" over ordinary shrimp of commerce).

61. *See In re Ewald*, 129 F.2d 340 (C.C.P.A. 1942) (cored half pear); *In re McKee*, 75 F.2d 636 (C.C.P.A. 1935) (frozen sliced meat); *Ex parte Grayson*, 51 U.S.P.Q. 413 (Pat. Off. Bd. App. 1941) (deveined shrimp). *See also In re McKee*, 75 F.2d 991 (C.C.P.A. 1935) (edible animal carcass having pigment branding thereon), and *Ex parte Mork*, 21 U.S.P.Q. 50 (Pat. Off. Bd. App. 1933) (artificially colored coal), for cases analogous to mechanical treatment.

62. *See Steinfur Patents Corp. v. William Beyer, Inc.*, 62 F.2d 238, 240 (2d Cir. 1932) (dark colored fur bleached and dyed light color); *Ex parte Mowry*, 110 U.S.P.Q. 389 (Pat. Off. Bd. App. 1955) (erosion/stable soil comprising natural soil and a water-soluble polymer); *Ex parte Shepherd*, 185 U.S.P.Q. 480, 483 (Pat. Off. Bd. App. 1974) (soil treated with fumigant and polymer gel).

63. *See Ex parte Hempel*, 55 U.S.P.Q. 429 (Pat. Off. Bd. App. 1942) (fish livers permeated with preservative patentable; *American Fruit* distinguished as relating to coated object).

64. *See Kayton*, *supra* note 10, at 10-11.

65. At least one purified "product of nature" case has made passing reference to *American Fruit*. *Ex parte Berkman*, 90 U.S.P.Q. 398, 401 (Pat. Off. Bd. App. 1950). *See also Kayton*, *supra* note 10, at 11.

66. *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453, 462-63 (2d Cir.), *cert. denied*, 209 U.S. 548 (1908) (the original septic tank); *Ex parte Prescott*, 19 U.S.P.Q.

peatedly upheld as patentable subject matter. However, *Guaranty Trust Co. v. Union Solvents Corp.*<sup>68</sup> suggests that there might be a distinction between processes utilizing living organisms and living organisms alone. In upholding the Weizmann process for the production of acetone and butyl alcohol by bacteriological fermentation, the court in *Guaranty Trust* made the following observation:

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. *Were the patent for bacteria per se, a different situation would be presented.* As before stated, the patent is not for bacteria per se. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. Undoubtedly there is patentable subject matter in the invention.<sup>69</sup>

While the above italicized sentence casts doubt on the patentability of living organisms alone, this issue was not before the Court.

Besides *Guaranty Trust* and the related cases involving processes employing living organisms, the only other case which possibly deals with the patentability of living organisms is *Funk Brothers Seed Co. v. Kalo Inoculant Co.*<sup>70</sup> In *Funk Brothers*, the inventor had obtained a patent for a leguminous plant inoculant formed of a composite of non-inhibitive strains of bacteria. Prior to the inventor's composite inoculant, the mixing of selected strains of bacteria had presented a problem in that the bacteria in the mixture tended to be mutually inhibitive. The inventor discovered that certain strains of bacteria were non-inhibitive so that they could be mixed together into a useful composite inoculant. The Court of Appeals, reversing the

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178, 180 (Pat. Off. Bd. App. 1932) (bacteriological production of butyl and isopropyl alcohol). See also *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934), cert. denied, 293 U.S. 576 (1934) (bacteriological purification of sewage); *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974) (process for producing antibiotic using previously unknown microorganism).

67. See *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 630 (S.D.N.Y. 1930) (process for producing scarlet fever antitoxin by injecting animal with sterile toxin and obtaining antitoxin therefrom). In *Lederle*, the Court also upheld process claims to the manner of making the sterile toxin utilizing a microorganism, as well as product claims to the toxin and antitoxin so produced.

68. 54 F.2d 400 (D. Del. 1931), aff'd per curiam, 61 F.2d 1041 (3rd Cir. 1932), cert. denied, 288 U.S. 614 (1933).

69. 54 F.2d at 410 (emphasis added).

70. 333 U.S. 127 (1948).

District Court, held that the composite inoculant defined a patentable invention.<sup>71</sup>

Justice Douglas, speaking for a majority of the Supreme Court,<sup>72</sup> reversed the Court of Appeals.<sup>73</sup> First, Justice Douglas noted that that the inventor could not patent the non-inhibition qualities of the bacteria because they were the "work of nature." Second, Justice Douglas stated that once it became known that certain strains of bacteria had a non-inhibitive quality, "the state of the art made the production of a mixed inoculant a simple step."<sup>74</sup> Next, Justice Douglas reasoned that there was no invention in the inventor's composite inoculant "unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention."<sup>75</sup> However, Justice Douglas concluded that to do so would allow a "patent to issue on one of the ancient secrets of nature now disclosed." Under this logic,<sup>76</sup> Justice Douglas held the claims to the mixed inoculant invalid as not disclosing an invention or discovery within the meaning of the patent statutes.<sup>77</sup>

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71. 161 F.2d at 986:

It was this contribution of non-inhibitive strains which successfully combine that brought about a new patentable composition. This was application of scientific knowledge to things existing in nature and the utilization of them in a desirable composite product which had not been previously achieved but which he did achieve and of which the public now has the benefit.

72. Justice Frankfurter disagreed with the reasoning of the majority opinion, and concurred solely on the ground that the description in the patent was vague and indefinite. 333 U.S. at 132-35. Justices Burton and Jackson dissented from the majority opinion in its entirety. *Id.* 135-38.

73. The majority opinion is so obscure and inarticulate that it has been cited for a number of different propositions. See, e.g., *Microbiological Plant Patents*, *supra* note 59, at 94 (composite inoculant unpatentable "aggregation"); *Products of Nature: The New Criteria*, 20 CATH. U. L. REV. 783, 787 (1971) (composite inoculant unpatentable "product of nature").

74. 333 U.S. at 132.

75. *Id.*

76. The logic of Justice Douglas in *Funk Bros.* is erroneous. As the Court of Appeals and the concurring opinion of Justice Frankfurter correctly observed, the inventor was not patenting a "law of nature", but instead a practical application thereof, namely a new composite inoculant of bacteria that did not exist in nature. By holding the patent to the composite inoculant invalid, Justice Douglas also violated the long standing principle that realization of the problem troubling the relevant industry is frequently more important to patentability than the solution thereof which usually follows in due course. See *Eibel Process Co. v. Minnesota & Ontario Paper Co.* 261 U.S. 45, 66-68 (1923).

77. It is questionable whether *Funk Bros.* is good law in view of 35 U.S.C. § 103 (1970), which was enacted subsequent to the decision. In *Funk Bros.*, Justice Douglas, in essence, used the discovery by the inventor as "prior art" against his composite inoculant. Such a practice is proscribed by the first sentence of 35 U.S.C. § 103, which requires that the subject

What was most extraordinary about the *Funk Brothers* decision was that the issue of the mixed inoculant as "living" subject matter was never raised. The Supreme Court based its decision regarding the validity of the patent on a different ground, namely, whether the mixed inoculant defined a patentable advance within the meaning of the statutes. Indeed, the Supreme Court seemed to assume that the mixed inoculant was statutory subject matter. Thus, the case law, other than the dicta in *Guaranty Trust*, suggests that living organisms are patentable subject matter under Section 101 of the patent laws.<sup>78</sup>

Perhaps, the issue that raises the greatest doubt as to the patentability of living subject matter under section 101 are the plant patent sections enacted in 1930.<sup>79</sup> Under these sections, one who discovers or who invents and reproduces through asexual processes a new and distinct variety of plant is entitled to patent protection.<sup>80</sup> Except for

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matter of the invention be viewed "as a whole" at the time of the inventor's creation thereof. *In re Kuehl*, 475 F.2d 658, 664-65 (C.C.P.A. 1973) (hydrocarbon cracking process using novel zeolite held patentable, although the process of using other zeolites in hydrocarbon cracking deemed old); *In re Mancy*, 499 F.2d 1289, 1292-93 (C.C.P.A. 1974) (process of producing antibiotic using unknown microorganism held patentable, although other microorganisms known to produce same antibiotic). *But cf.* *Parker v. Flook*, 98 S.Ct. 2522 (1978), where the Supreme Court has incorrectly stated that a newly discovered algorithm is to be treated as "prior art." Furthermore, Justice Douglas in *Funk Bros.* seems to imply that if the inventor had accidentally created the composite inoculant, the patent might have been upheld. Such a proposition is contrary to the second sentence of 35 U.S.C. 103, which prevents the patentability of the invention from being affected by the manner in which it was made.

78. *See Ex parte Bergy*, 197 U.S.P.Q. 78, 81 (Pat. Off. Bd. App. 1976) (dissenting opinion): The Court [in *Funk Bros.*] seems to have acted on the assumption that the subject matter of the controversy was, like any other subject matter, not to be singled out for any special determination, but to be evaluated for patentability in the ordinary manner. At the very least, the majority holding can be said to be neutral on the subject of whether strains of bacteria fall within the statutory classes of patentable subject matter.

79. Now codified as 35 U.S.C. §§ 161-64 (1970).

80. *Id.* § 161. *See generally* Hayman, *Botanical Plant Patent Law*, 11 Clev.-Mar. L. Rev. 430 (1962), for a general discussion of the plant patent sections. For the most part, plant patents are governed by the sections relating to utility patents. *See, e.g., Yoder Bros. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1378-79 (5th Cir. 1976), *cert. denied*, 429 U.S. 1094 (1977) ("obviousness" provision of 35 U.S.C. § 103 applicable); *In re LeGrice*, 301 F.2d 929, 935 (C.C.P.A. 1962) ("printed publication" provision of 35 U.S.C. § 102(b) applicable); *See also Nicholson v. Bailey*, 182 F. Supp. 509 (S.D. Fla. 1960) ("knowledge or use of others" provision of 35 U.S.C. § 102(a), "public use" provision of 35 U.S.C. § 102(b) and "notice of patent" provision of 35 U.S.C. § 287 applicable); *Cole Nursery Co. v. Youdath Perennial Gardens, Inc.* 17 F. Supp. 159 (N.D. Ohio 1936), *appeal dismissed*, 101 F.2d 1007 (6th Cir.



certain specified classes of plants,<sup>81</sup> there is nothing in the plant patent sections to expressly exclude other forms of living subject matter from the protection of the patent laws. However, there are subtle indications that, until the plant patent sections were enacted, no form of living organism was within the boundaries of the patent laws. For instance, the legislative reports on the plant patent sections of both the Senate and House state the following:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. The bill will remove the existing discrimination between plant developers and industrial inventors.<sup>82</sup>

This stated objective of the plant patent sections has been noted several times by the courts<sup>83</sup> and at least one court has assumed in dictum that plants did not come within the patent laws until the plant patent sections were enacted.<sup>84</sup> Thus, the plant patent sections could indicate that Congress did not intend to permit patent protection for other forms of living subject matter, unless by express legislative enactment.<sup>85</sup>

However, there are other indications that Congress was not expressing an opinion on the patentability of all things that could be

1939) ("public use" provision of old 35 U.S.C. § 31 [now 35 U.S.C. § 102(b)] applicable).

However, there are a number of exceptions, such as the satisfaction of certain formal requirements and the manner of infringing a plant patent. *See* 35 U.S.C. § 162 (1970) (plant patent application need not fully comply with the formal requirements of 35 U.S.C. § 112 if the description is as complete as is reasonably possible); *Cole Nursery Co. v. Youdath Perennial Gardens, Inc.*, 17 F. Supp. 159 (N.D. Ohio 1936), *appeal dismissed*, 101 F.2d 1007 (6th Cir. 1939) (patented plant must be either totally appropriated or cuttings taken therefrom for infringement).

81. *See* 35 U.S.C. § 161 (1971) (tuber propagated plants and plants found in an uncultivated state).

82. S. REP. No. 315, 71st Cong., 2d Sess. 1 (1930); H.R. REP. No. 1129, 71st Cong., 2d Sess. 1 (1930).

83. *E.g.*, *In re LeGrice*, 301 F.2d 929, 932 (C.C.P.A. 1962); *Kim Bros. v. Hagler*, 167 F. Supp. 665, 670 (S.D. Cal. 1958), *aff'd*, 276 F.2d 259 (9th Cir. 1960).

84. *Yoder Bros. v. California-Fla. Plant Corp.*, 537 F.2d 1347, 1377 (5th Cir. 1976), *cert. denied*, 429 U.S. 1094 (1977).

85. The best argument for the proposition that plants were not patentable prior to 1930 can be found in a little known and little discussed transitory provision *See* Act of May 23, 1930, ch. 312, § 5, 46 Stat. 376, which precluded patent protection for plants introduced prior to May 23, 1930.

considered "living" by enacting the plant patent sections. In *In re Arzberger*,<sup>86</sup> the CCPA had an opportunity to rule on the question of whether bacteria are "plants" within the meaning of the plant patent sections. In holding that bacteria are not "plants" within the plant patent sections, the CCPA noted that, while bacteria might be scientifically classified as "plants," the common meaning of the word did not encompass bacteria. The CCPA then examined the legislative history of the plant patent sections and noted that Congress was thinking of the word "plants" in its popular and ordinary sense and not in its scientific sense. Thus, *Arzberger* could support the argument that while Congress may have expressed a view as to the patentability of certain types of living subject matter in the popular sense, e.g. plants, it expressed no view as to the patentability of other forms of living subject matter in the broader scientific sense, e.g. microorganisms.<sup>87</sup>

Another plausible position is that, in enacting the plant patent sections, Congress expressed no view as to the patentability of living subject matter under the currently existing provisions of the patent laws. First, Congress may have enacted the plant patent sections in order to alleviate certain formal requirements of the existing patent laws which Congress believed impaired plant patent protection.<sup>88</sup> Secondly, Congress may have wished to expressly sanction plant patent protection in order to clarify any potential misunderstandings under prior existing law.<sup>89</sup> Whatever Congress meant in enacting the plant patent sections, the legislative intent is sufficiently ambiguous to support either the patentability or non-patentability of other forms of living subject matter other than plants.

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86. 112 F.2d 834 (C.C.P.A. 1940). See generally *Microbiological Plant Patents*, *supra* note 59, which criticizes the holding in *Arzberger*.

87. See *Ex parte Bergy*, 197 U.S.P.Q. 78, 82 (Pat. Off. Bd. App. 1976) (dissenting opinion): Of the various acknowledged nonstatutory categories, plants are most akin to the living organisms. Both materials are alive. However, that is where the similarity stops. As held in the *Arzberger* case, living organisms (bacteria) are not plants within the meaning of the plant statute. While bacteria may possess some of the characteristics of plants, the word "plant" is used in its popular sense and not in its scientific sense since the statute was designed for the benefit of agriculturists and horticulturists. Thus, the exclusion of plants from 35 U.S.C. [§ 101] does not necessarily apply to bacteria.

88. See *In re Chakrabarty*, 571 F.2d 40, 42-43 (C.C.P.A. 1978) (argument by appellant).

89. Because the courts, as in *Funk Bros.*, *supra* notes 72-80 and accompanying text, appear to implicitly assume that living subject matter other than plants was patentable, such an argument, though weak, is not entirely without merit.

## III. THE PATENTABILITY OF MICROORGANISMS: THE CCPA SPEAKS OUT

Prior to the decisions of *In re Bergy*<sup>90</sup> and *In re Chakrabarty*,<sup>91</sup> the CCPA had given no indication that it was favorably inclined to the idea of granting patents for any form of living subject matter other than plants. In *In re Mancy*,<sup>92</sup> the applicants claimed a process for producing the antibiotic daunorubicin by aerobically cultivating a certain microorganism known as *streptomyces bifurcus*. This strain of microorganism was "new" in that it was not disclosed by any of the references cited by the examiner. The Patent Office Board of Appeals affirmed the rejection of the examiner that the applicants' invention was obvious under Section 103 in view of the cited references. The CCPA reversed the Patent Office Board of Appeals by holding the applicants' invention nonobvious over the cited references. In so deciding, the CCPA concluded its opinion with the following comment:

Here [applicants] not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature."<sup>93</sup>

While the above statement is clearly dicta, the CCPA in *Mancy* seemed to give an indication that it would not uphold the patentability of other forms of living subject matter besides plants.<sup>94</sup>

In *In re Merat*,<sup>95</sup> the applicant attempted to patent both a process for producing normal chickens from dwarf hens and normal cocks, and the chicken so produced by the process. The examiner rejected the claims under Section 101 as being directed to non-statutory subject matter. The Patent Office Board of Appeals affirmed this ground of rejection and added two new grounds; namely, that the claims were obvious under Section 103 over cited references and

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90. 563 F.2d 1031 (C.C.P.A. 1977).

91. 571 F.2d 40 (C.C.P.A. 1978).

92. 499 F.2d 1289 (C.C.P.A. 1974).

93. *Id.* at 1294.

94. See also Behr, *The Prescient Microbe or Where to Deposit a Foreign Body*, 57 J. PAT. OFF. Soc'y 28, 29-30 (1975) (no reasonable possibility in any jurisdiction for protection of microorganisms *per se*).

95. 519 F.2d 1390 (C.C.P.A. 1975).

were indefinite under Section 112. The CCPA affirmed on the Section 112 grounds and, therefore, found it unnecessary to discuss the non-statutory subject matter rejection under Section 101. Thus, the issue of the patentability of living organisms other than plants remained open.

#### A. *In re Bergy*

In view of the, at best, neutral comments in *Mancy* and *Merat*, the CCPA proceeded with its momentous decision in *In re Bergy*.<sup>96</sup> In *Bergy*, the applicants disclosed a microbiological process for preparing the antibiotic lincomycin by utilizing a newly discovered microorganism, *streptomyces vellosus*. As originally filed, the application had claims only to the process of preparing the antibiotic by the newly discovered microorganism. However, the applicant later filed an additional claim to a "biologically pure culture of the microorganism *streptomyces vellosus*" having certain identifying characteristics. The claim to the biologically pure culture was rejected solely on the ground that it was non-statutory subject matter under Section 101 as being a "product of nature."<sup>97</sup> Applicant was unsuccessful in convincing the examiner that the biologically pure culture was not a "product of nature", and therefore appealed to the Patent Office Board of Appeals.

The Patent Office Board of Appeals affirmed the examiner's rejection of the claim directed to the biologically pure culture of the microorganism.<sup>98</sup> However, it based its rejection not on the ground that the pure culture was a "product of nature", but solely on the theory that a "living organism" was non-statutory subject matter within the meaning of Section 101. First, the Patent Office Board of Appeals reasoned that Section 101 should be "strictly construed and, when so interpreted, precludes the patenting of a living organism."<sup>99</sup> Next, the Patent Office Board of Appeals pointed to the plant patent sections as evidencing the legislative view that living organisms, whether plants or microorganisms, were not "manufactures" or "compositions of matter" within the meaning of

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96. 563 F.2d 1031 (C.C.P.A. 1977).

97. Because the impure culture of microorganism existed in nature, it is easy to see why the "product of nature" doctrine was brought into play.

98. *Ex parte Bergy*, 197 U.S.P.Q. 78 (Pat. Off. Bd. App. 1976).

99. *Id.* at 79.

Section 101.<sup>100</sup> By holding applicant's biologically pure culture non-statutory subject matter on the ground that it was directed to a "living organism," the Patent Office Board of Appeals found it unnecessary to reach the "product of nature" issue.<sup>101</sup>

When the case reached the CCPA, Judge Rich, speaking for a plurality of the court,<sup>102</sup> found it necessary to clarify the issue presented since the Patent Office Board of Appeals had switched its rejection from the "product of nature" ground of the examiner to the newly raised "living organism" ground. From a review of the proceedings in the Patent Office, Judge Rich concluded that the "product of nature" issue had been abandoned and was no longer in the case. However, because of the somewhat muddled nature of the earlier proceedings, Judge Rich still found it necessary to make the following observation:

However, since the solicitor indicated at oral argument that he was not sure the Board had removed it entirely, we state that we find it wholly lacking in merit. The biologically pure culture of claim 5 clearly does not exist in, and is not found in, and is not a product of "nature." It is man-made and can be produced only under carefully controlled laboratory conditions.<sup>103</sup>

Having disposed of the "product of nature" issue, Judge Rich found it necessary to clarify the prior CCPA decisions of *Merat* and

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100. *Id.* In the Patent Office Board Of Appeals' view, a "liberal interpretation" of 35 U.S.C. § 101 would raise the specter of the patentability of new type of insects or new varieties of animals produced by selective breeding and cross-breeding. For arguments as to why this would not be necessarily so, see notes 143-45, *infra*, and accompanying text.

101. 197 U.S.P.Q. at 80. One Board member dissented. Portions of his opinion have been reproduced elsewhere. See notes 80, 89, *supra*.

102. Judge Markey joined Judge Rich's opinion. Judge Kashiwa, sitting by designation in place of Judge Lane, concurred separately as to the "narrow confines" of Judge Rich's opinion. 563 F.2d at 1039. Judges Miller and Baldwin dissented.

103. *Id.* at 1035. While Judge Rich appeared to conclude that the "product of nature" question was no longer in issue, the preceding statement necessitates a few remarks. Although the biologically pure culture might have been man-made and produceable only under certain specified laboratory conditions, this fact alone did not resolve the issue of whether the pure culture was a patentable advance over the naturally existing unpurified culture. As even prior CCPA decisions pointed out, mere purification of what existed in nature might not be patentable unless there was a difference in "kind and not degree," e.g. the pure culture resulted in some unexpected property. See notes 45-49, *supra*, and cases cited therein. However, from what was presented in the record of the case, there is very little to indicate, one way or the other, how this question should have been resolved.

*Mancy*. With respect to *Merat*, Judge Rich noted that the question of patentable subject matter under Section 101 had been left open. In regard to *Mancy*, Judge Rich explained that the CCPA was concerned there with a hypothetical organism that was "pre-existing and merely plucked from the earth, . . . a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed."<sup>104</sup> To whatever extent the dictum in *Mancy* might support the proposition that microorganisms were unpatentable subject matter, Judge Rich specifically retreated from such a position.

Having disposed of preliminary matters, Judge Rich then moved to the main issue of whether the "fact that the biologically pure culture, *as claimed*, is *alive* removes it from the categories of inventions enumerated in Section 101."<sup>105</sup> In concluding that it did not, Judge Rich presented two different arguments. The first argument was by analogy to the *Guaranty Trust* line of cases which had held processes utilizing living organisms to be patentable subject matter. Because processes utilizing living organisms had been held patentable subject matter, Judge Rich reasoned that a claim directed to a microorganism as a "manufacture" or "composition of matter" must likewise be patentable, unless there be some distinction between the statutory classes. However, as Judge Rich correctly pointed out: "The statute makes no distinction between manufactures and compositions on the one hand and processes on the other."<sup>106</sup>

While Judge Rich's argument by analogy has logical merit, the CCPA's prior decisions unfortunately lend little support to it. As noted by the dissenters in *Bergy*, what logic dictates and what case law requires are two entirely different matters.<sup>107</sup> As prior CCPA decisions clearly indicate in other areas, subject matter which is

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104. 563 F.2d at 1036.

105. *Id.* at 1035.

106. *Id.* at 1037. In finding no express distinction between the statutory classes, Judge Rich also rejected any suggestion by the Patent Office Board of Appeals that 35 U.S.C. § 101 must be "strictly construed" to prohibit the patentability of microorganisms.

107. 563 F.2d at 1041 (dissenting opinion): "However, this court has pointed out that claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not. [Citations omitted]. Similarly here, the fact that claims directed to a process of *using* microorganisms constitute patentable subject matter does not logically compel the conclusion that claims to biologically pure cultures of microorganisms are patentable."

statutory when claimed in a certain context may yet be non-statutory when claimed alone.<sup>108</sup> Thus, Judge Rich's "argument by analogy" is premised on a very uncertain case law foundation.<sup>109</sup>

The second argument of Judge Rich in support of patentability seems to be based on the proposition that there is a distinction between the meaning of the word "living" as broadly used and as used under the patent statutes. As stated by Judge Rich:

The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.<sup>110</sup>

Because microorganisms were "a useful and technological art," Judge Rich felt that they should not be denied patent protection on the formalistic ground that they were "alive." Therefore, Judge Rich held the distinction between microorganisms and chemical compounds based on the animateness of the former to be "without legal significance."

There is at least implicit support for Judge Rich's second argument in the case law. As noted previously, the CCPA in *Arzberger* stated that there was a distinction between the scientific and common place meaning of certain words such as "plants." Taking that analogy one step further, it could be argued that microorganisms, while "living" in the broad scientific sense, are not "living" in the narrow common place or patent law sense of the word.<sup>111</sup> In characterizing the fears of the Patent Office Board of Appeals as "far fetched," Judge Rich appears to adopt this reasoning when he observed that the question of the patentability of "plants, animals and

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108. See *In re Flook*, 559 F.2d 21 (C.C.P.A. 1977), *rev'd sub nom.*, *Parker v. Flook*, 98 S.Ct. 2522 (1978) (process utilizing non-statutory "algorithm" to modify convention manufacturing system held statutory subject matter); *In re Miller*, 418 F.2d 1392, 1396 (C.C.P.A. 1969) (non-statutory "printed matter" entitled to patentable weight when used with statutory "manufacture"). The Supreme Court, despite protestations to the contrary, has cast severe doubt on the preceding proposition. See 46 U.S.L.W. at 4793.

109. See *Kayton*, *supra* note 10, at 4 (argument by analogy relatively weak in view of controlling case law).

110. 563 F.2d at 1038.

111. See note 89 *supra*, and accompanying text.

insects created by man" was not before the court.<sup>112</sup>

Surprisingly, Judge Rich's opinion quickly discounted the Patent Office Board of Appeals argument as to the influence of the plant patent sections:

Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction. We are not here concerned with the interpretation of the Plant Patent Act as this Court was in *In re Arzberger*, supra, which simply held that that Act did not encompass bacteria.<sup>113</sup>

It was these plant patent sections which formed the primary focus for Judge Miller's dissenting opinion that the biologically pure culture of the microorganism was non-patentable.<sup>114</sup> First, Judge Miller found the legislative history of the plant patent sections to be extremely persuasive that plants were not covered by the predecessor of Section 101 until the plant patent sections were enacted. Secondly, he found Judge Rich's attempts "to distinguish between microorganisms and more complex living things" to be "purely gratuitous" and unpersuasive. As Judge Miller perceived the situation, the plant patent sections, as well as the legislative history pertaining thereto, supported the conclusion that no living organism was intended by Congress to be within the scope of Section 101.<sup>115</sup> Finally, Judge Miller referred to the Plant Variety Protection Act of 1970<sup>116</sup> as further evidence that Congress did not intend living organisms to be within the terms "manufacture" and "composition of matter" as defined in Section 101.

Although Judge Miller's argument is certainly reasonable, it is not irrefutable. As noted previously, there is a logical basis, perhaps not clearly set forth in Judge Rich's opinion, for distinguishing be-

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112. 563 F.2d at 1038.

113. *Id.* at 1038-39, citing *In re Arzberg*, 112 F.2d 834 (C.C.P.A. 1940).

114. *Id.* at 1039-41.

115. Judge Miller's position was based essentially on two arguments. First, to hold that living organisms were patentable prior to the enactment of the plant patent sections would render those sections superfluous. Second, if plants were originally patentable subject matter, the plant patent sections would constitute a repeal by implication of certain formal requirements still applicable to other patentable subject matter. *Id.* at 1039.

116. Now codified as 7 U.S.C. § 2321 *et seq.*



tween microorganisms and more complex living organisms. Also, reliance on the plant patent sections as evidence of legislative intent on the patentability of all forms of living subject matter is an extremely slippery proposition. The legislative history of the plant patent sections is, at best, ambiguous on the point. Furthermore, what case law there is, both prior to and after enactment of the plant patent sections, gives no indication that microorganisms were considered outside the scope of the patent laws.<sup>117</sup> As noted by Judge Rich, the patentability of microorganisms was probably never considered when Congress enacted the plant patent sections.<sup>118</sup>

### B. *In re Chakrabarty*

When the CCPA rendered its decision in *In re Chakrabarty*,<sup>119</sup> it progressed significantly, though perhaps unconsciously, beyond its holding in *Bergy*.<sup>120</sup> In *Chakrabarty*, the applicant's invention was directed to a novel, man-made microorganism. Specifically, the applicant had "genetically engineered" a new strain of bacteria having an increased capacity to degrade various components of crude oil by transmitting to a single microorganism a plurality of compatible extrachromosomal units known as "plasmids."<sup>121</sup> The modified organism created by the applicant was particularly important in that it could be used to control oil spills.

The examiner rejected the claims directed to the modified microorganism under Section 101 as being drawn either to "products of nature",<sup>122</sup> or to "living organisms." The Patent Office Board of Appeals reversed as to the first ground, but affirmed as to the second ground presented by the examiner. The reasons presented by the Patent Office Board of Appeals were essentially those rejected in *Bergy*.<sup>123</sup>

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117. See notes 68-80, *supra*, and accompanying text.

118. See 563 F.2d at 1039.

119. 571 F.2d 40 (C.C.P.A. 1978).

120. See Kayton, *supra* note 10, at 4 (different technology in *Chakrabarty* makes case genuinely different with respect to 35 U.S.C. § 101 from *Bergy*).

121. By transmitting the plasmids to a single microorganism, applicant overcame the prior art problem of mutual inhibition or destruction which accompanied a mixture of the various strains of microorganisms.

122. The "product of nature" rejection is particularly odd in that the modified microorganism did not exist in nature.

123. *In re Chakrabarty*, 571 F.2d 40, 42 (C.C.P.A. 1978).

The CCPA reversed the Patent Office Board of Appeals decision with a terse opinion by Judge Rich speaking for a plurality of the Court. As Judge Rich saw it, the sole reason advanced for the Patent Office Board of Appeals' contention was that the new bacterium was "alive." He therefore reasoned that the present case and *Bergy* were indistinguishable on the issue before the Court. Having ruled in *Bergy* that a biologically pure culture of microorganism was patentable subject matter, Judge Rich found that decision to be controlling precedent for the patentability of a novel, man-made microorganism.<sup>124</sup>

The rather revolutionary step that the CCPA was taking in *Chakrabarty* was highlighted in the dialogue between the concurring opinion by Chief Judge Markey and the dissenting opinion by Judge Baldwin. Chief Judge Markey stated the issue as "whether a man-made invention, admittedly novel, useful, and unobvious, is unpatentable because, and only because, it is 'alive.'"<sup>125</sup> According to Chief Judge Markey, there were but two sources for "manufactures" and "compositions of matter," namely God (nature) and man. Because the invention before the Court was a "manufacture" by man, it was therefore "squarely within the language of the statute."<sup>126</sup> In rebuttal to the position of the Patent and Trademark Office that the word "dead" should be inserted into the statute, Chief Judge Markey observed, "The statute is not ambiguous. No Congressional intent to limit patents to dead inventions lurks in the lacuna of the statute, and there is no grave or compelling circumstance requiring us to find it there."<sup>127</sup> Chief Judge Markey found the plant patent sections of no weight in determining what the Congressional intent would have been had it been confronted with a modified microorganism. Furthermore, he felt it was unnecessary to assume that plants were within the scope of the patent statutes prior to the 1930 enactment of the plant patent sections. Because the modified bacteria fell squarely within the terms "manufacture" or "composition of matter" as enacted by Congress, Chief Judge Markey felt that to interpret Section 101 otherwise would "defeat the fundamental purpose of the Constitution, and of the patent laws enacted thereunder."<sup>128</sup>

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124. *Id.* at 43.

125. *Id.* at 44.

126. *Id.*

127. *Id.*

In response to Chief Judge Markey's argument, Judge Baldwin raised for the first time the test set forth in *American Fruit*. In addition to Chief Judge Markey's categories of "products of nature" and "manufactures," *American Fruit*, according to Judge Baldwin, added an intermediate category of something not a "product of nature," yet not sufficiently modified so as to be a statutory "manufacture." After quoting the relevant portions of *American Fruit*, Judge Baldwin summarized the case by stating that "a modified natural product does not become statutory subject matter until its essential nature has been substantially altered."<sup>129</sup>

In resolving the issue of whether the applicant's modified bacteria had been changed in its "essential nature," Judge Baldwin made the curious assumption that the "essential nature" of the unmodified microorganism was "its animateness or life." However, the applicant had not changed "this essential nature" in that he had not created "new life." While the applicant's genetic grafting may have removed the new microorganism from the classification of "a mere product of nature," Judge Baldwin felt that such a modification did not render the new microorganism patentable subject matter under Section 101.<sup>130</sup>

After analyzing Judge Baldwin's opinion, one has to wonder why the "essential nature" of the unmodified microorganism was its "animateness," as opposed to some other feature or quality.<sup>131</sup> Under *American Fruit*, it would seem that the applicant's genetically modified microorganism clearly satisfies the test set forth. A microorganism which has been modified so as to digest oils, which the unmodified microorganism was unable to do, would seem to be the type of "new distinctive form, quality, or property" to which *American Fruit* alluded.<sup>132</sup> To say then that the "essential nature"

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128. *Id.*

129. *Id.* at 45.

130. *Id.* Judge Miller repeated essentially his dissenting opinion in *Bergy*. *See id.* at 45-47.

131. *See Kayton, supra* note 10, at 10:

For example, suppose Chakrabarty taught in his specification that, in addition to being a greedy oil-eater, the new (or altered) bacterium has other radically different characteristics which happen to be of no interest to us (e.g., it may be opaque rather than transparent, it may be larger, it may be hour-glass shaped instead of oval, or it may be one millimicron wider).

132. *See id.* at 9: "Using the criterion of *American Fruit*, \*\*\* the Chakrabarty bacterium fits precisely into the Court's definition of novel statutory subject matter."

of the microorganism was its "animateness" seems to inject a subjective determination into the test of *American Fruit* without any clear reason for doing so.<sup>133</sup>

#### IV. IMPLICATIONS OF THE PATENTABILITY OF MICROORGANISMS

##### A. *Are Other Living Organisms Patentable Subject Matter?*

Admittedly, the decisions rendered by the CCPA in *Bergy* and *Chakrabarty* are binding only in that court. Other courts confronted with the infringement of patents directed to microorganisms may reach the same conclusions asserted by the dissenting opinions in those cases. Assuming that *Bergy* and *Chakrabarty* remain valid,<sup>134</sup> what effect will those decisions have on the patentability of other living organisms? The majority of the CCPA does not necessarily evidence a uniformity of thought. Judge Rich's opinion in *Bergy* suggests that he would draw the line between microorganisms, or entities similar thereto, on the one hand, and complex living organisms on the other. In contrast, Chief Judge Markey's opinion in *Chakrabarty* supports the position that as long as the organism is "man-made," the complexity of the organism created is irrelevant. Finally, Judges Miller and Baldwin clearly reject the patentability of any living organism whether it be denominated complex or not.

Professor Kayton has attempted to predict the patentability of other living organisms produced by cloning techniques and recombinant DNA research by utilizing the *American Fruit* test.<sup>135</sup> Under *American Fruit*, Kayton believes that a cloned organism is unpatentable subject matter.<sup>136</sup> Such a position would probably be sup-

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133. *See id.* at 11-12:

Life or lack of life is simply not involved in the analysis under *American Fruit* unless you adopt Judge Baldwin's totally gratuitous approach which says it is the form, or quality, or property called "life" which has to be changed (presumably into death?) in order to have an article of manufacture. To take that approach is to convert a conclusion into the premise of an argument and then to jump from that premise immediately to the conclusion.

134. The United States Patent and Trademark Office has petitioned for certiorari in the *Bergy* case. 376 PAT. T.M. & COPR. J. D-1 (1978). The Supreme Court has recently summarily vacated the judgment in the *Bergy* case and remanded for further consideration in light of its decision in *Parker v. Flook*, 98 S. Ct. 2522 (1978). *Parker v. Bergy*, 98 S. Ct. 3119 (1978). However, in view of the dissimilarities of the subject matter involved in *Parker v. Flook* and *Bergy*, it is unlikely that the CCPA will change its mind on the patentability of microorganisms.

135. Kayton, *supra* note 10, at 12-13.

136. *Id.* at 12.

portable by even Chief Judge Markey because, by definition, the cloned organism has not been changed at all.<sup>137</sup> Indeed, as noted by Kayton, all the judges of the CCPA would undoubtedly hold a cloned organism unpatentable as being neither new nor novel within the meaning of Sections 101 and 102.<sup>138</sup>

In contrast, Professor Kayton believes that the products of recombinant DNA research are clearly patentable subject matter in that the organisms so created are the result of significant modifications.<sup>139</sup> However, it is unclear whether a majority of the CCPA would hold *all* products of recombinant DNA research patentable subject matter. Because the organism which is the product of recombinant DNA research is "man-made," Chief Judge Markey would probably hold it to be patentable subject matter. However, if Judge Rich's opinion in *Bergy* can be accepted at face value, it would seem that Judge Rich would hold a complex organism, which is the product of recombinant DNA research, to be non-patentable subject matter.<sup>140</sup> Assuming that Judges Baldwin and Miller maintain their stated positions in *Bergy* and *Chakrabarty*, the patentability of the products of recombinant DNA research would seem to depend on the type of organism created.

A case would go far towards resolving the doubt by answering the thorny question of the patentability of animals produced by breed-

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137. *Id.*: "Is the living clone itself statutory subject matter? Under *American Fruit* it probably is not, because it is not anything that has been changed radically. In fact, it is identical by definition (because of its identical genetic structure) to the parent from which it was cloned."

138. *Id.* at 12-13:

However, even if the clone were statutory subject matter, it would be unpatentable for lack of novelty under § 102 of the statute. By definition, the clone will be structurally identical to its parent or to what its parent was at the same age. Nothing about it, therefore, can be considered to be new.

139. *Id.* at 12:

If the product of the plasmid transfer in the *Chakrabarty* sense is statutory, then anything created through recombinant DNA engineering is statutory, *a fortiori*. Even if the product of a plasmid reconstruction or transfer is non-statutory, it would appear that a product of recombinant DNA construction could be so radically different a creature that even under Judge Baldwin's standards it would be statutory unless his criterion categorically eliminates any form of living organism from the statutory classes.

140. The distinction between complex organisms on the one hand and microorganisms or entities similar thereto on the other seems to be absolutely necessary for the logical support of Judge Rich's opinion in *Bergy*. See notes 112-14, *supra*, and accompanying text.

ing and cross-breeding, an issue left open by the CCPA in *Merat*.<sup>141</sup> A combination of the apparent position of Judge Rich with the clearly stated positions of Judges Miller and Baldwin, would apparently result in a holding that an animal that is the product of breeding and cross-breeding constitutes unpatentable subject matter.<sup>142</sup> The only judge who might advocate patentability would be Chief Judge Markey. However, even Chief Judge Markey might determine such an animal to be unpatentable subject matter if the word *primarily* were inserted before the phrase "man-made."<sup>143</sup> Therefore, the fear expressed by the Patent and Trademark Office in the *Bergy* case of the potential patentability of more complex living organisms appears to be groundless.

### B. *What Are the Outer Limits of Patentable Subject Matter?*

Like the issue of the patentability of other living organisms besides microorganisms, the decisions of *Bergy* and *Chakrabarty* imply a division of thinking on the outer limits of patentable subject matter in general. On the one hand, there is the group, primarily represented by the Patent and Trademark Office and the two dissenting judges in *Bergy* and *Chakrabarty*, which argues that the outer limits of patentable subject matter should be strictly construed. These strict constructionists advocate that when Congress enacted the statutory classes of subject matter, it intended only to protect those inventions which were closely akin to conventional technology. Accordingly, to construe the statutory classes of patentable subject matter liberally would be to invade a domain expressly left to Congress. If certain meritorious inventions, such as novel microorganisms, happen to fall outside the statutory classes, the strict constructionists believe that it is the duty of Congress to expressly bring these new technologies within the ambit of the patent statutes.<sup>144</sup>

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141. See note 97, *supra*, and accompanying text.

142. I.e., a combination of complex living organisms are unpatentable (Judge Rich) and all living organisms besides plants are unpatentable (Judges Baldwin and Miller).

143. Normally, an animal produced by breeding and cross-breeding is substantially the result of non-human forces. However, if substantial human ingenuity or intervention was required to produce the new animal, Chief Judge Markey might well consider such a new animal patentable subject matter. The interpretation of "obvious" under 35 U.S.C. § 103 may also pose a significant barrier to the patentability of such animals.

144. Regrettably, it seems that the Supreme Court has also taken this "head in the sand" approach to patentable subject matter. See *Parker v. Flook*, 98 S. Ct. 2522, 2529 (1978): "It

In contrast, the liberal constructionists, who are primarily represented by the majority of the court in *Bergy* and *Chakrabarty*, believe that the outer limits should be generously construed to encompass a broad class of new and useful inventions. The liberal constructionists argue that when Congress enacted certain statutory classes of subject matter, it did not intend to have these enumerated classes rigidly interpreted so as to exclude radical advances in the technological arts. The statutory classes of subject matter were to serve merely as broad guidelines since Congress clearly realized that newer forms of technology might well outstrip conventional notions of patentable subject matter. To hold otherwise, the liberal constructionists say, would require Congress to engage in the hopeless task of continually modifying its definition of patentable subject matter to conform to the advances in technology.

Unless Congress expressly states otherwise, the liberal constructionist view seems to be the preferable one. First, the very nature of technological advance militates against an inflexible interpretation of the statutory classes of patentable subject matter.<sup>145</sup>

Second, the continual conflict over what is and is not patentable subject matter has tended to obscure the more important question of whether the given invention constitutes a meritorious advancement of the public's knowledge. Indeed, the "product of nature" line of cases suggest that the courts may be confusing the question of what constitutes patentable subject matter with the question of whether the subject matter represents a patentable advance in the art.<sup>146</sup>

Third, the standards enunciated by the courts determining what constitutes patentable and non-patentable subject matter appear to

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is our duty to construe the patent statutes as they now read, in light of our prior precedents, and we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."

145. See *Computer Programs and Subject Matter Patentability*, 6 RUTGERS J. COMP. & L. 1, 21 n.135 (1977): "Inventions by their very nature contain unforeseen elements. There is therefore good reason for some degree of flexibility in patent statute administration, for one would not wish to see the invention of tomorrow placed in yesterday's unsuitable category."

146. See generally *Products of Nature*, *supra* note 75 (criteria employed to determine patentability of "products of nature" are imprecise and confusing). A majority of the Supreme Court seems to have also totally confused the issue of patentable subject matter under 35 U.S.C. § 101 with the question of obviousness under 35 U.S.C. § 103. See *Parker v. Flook*, 98 S. Ct. 2522, 2526-28 (1978). Such confusion has not gone unnoticed by the remainder of the Supreme Court. *Id.* at 2530-31 (dissenting opinion).

place too much weight on a subjective determination.<sup>147</sup> Moreover, the test of whether a certain item constitutes patentable subject matter within the meaning of Section 101 appears to have been employed in the past for reasons inconsistent with the statutory purpose. For instance, the Patent and Trademark Office has apparently utilized the Section 101 defense to alleviate what it perceives as burdensome administrative problems.<sup>148</sup> However, as Chief Judge Markey observed in *Chakrabarty*, "Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology."<sup>149</sup>

Finally, as noted in the above quotation, if certain technologies are denied patent protection for failure to be within the enumerated statutory classes of patentable subject matter, the patent laws' primary purpose of encouraging disclosure to the public of meritorious inventions<sup>150</sup> may be thwarted. If particular inventions are determined to fall outside these specified classes, those inventors will seek other forms of protection, such as trade secrets. For technologies which are easily the subject of "reverse engineering,"<sup>151</sup> the problem will not be so great. However, for those technologies as sophisticated as the genetically engineered microorganism of *Chakrabarty*, the public is going to be denied important and useful information if such inventions are protected as trade secrets in response to the denial of patent protection.<sup>152</sup>

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147. *Products of Nature*, *supra* note 75, at 788.

148. See 371 PAT. T.M. & COPR. J. D-1, D-7 & n.24 (1978) (brief of Government in *Parker v. Flook* 98 S.Ct. 2522 (1978)). The intense effort by the Patent and Trademark Office to employ 35 U.S.C. § 101 to nullify potentially meritorious subject matter has evoked on one occasion allegations by the CCPA of unprofessional conduct. See *In re Freeman*, 573 F.2d 1237, 1243 n.2 (C.C.P.A. 1978).

149. 571 F.2d 40, 44 (C.C.P.A. 1978).

150. See note 2 *supra*.

151. "Reverse engineering," e.g., analyzing the publicly available product to divine the secret process, has always been a proper method for discovering a trade secret. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974).

152. In the case of "genetically engineering," the man-made microorganism may provide little information on the process used to produce it, therefore "reverse engineering" could require years of research. See *Microbiological Plant Patents*, *supra* note 59, at 90, which describes the problems created by the Aureomycin patents due to the inability to patent the microorganisms prior to *Bergy* and *Chakrabarty*. See generally Robbins, *Patents for Micro-*



A broad outer limit of patentable subject matter does not necessarily mean that there are no articulable boundaries at all. Even the liberal constructionist recognizes that when Congress enacted the statutory classes of patentable subject matter, Congress intended to protect only practical applications of theory rather than the mere discovery of a law of nature or natural principle. By holding technologically useful microorganisms to be patentable subject matter, the CCPA in *Bergy* and *Chakrabarty* did not exceed this legislative mandate. Indeed, the reasoning in those two cases suggests that there may yet be limits within even the broadest outer boundaries.

## V. CONCLUSION

The CCPA decisions of *Bergy* and *Chakrabarty* illustrate the present controversy over what constitutes patentable subject matter. Although those two decisions were primarily concerned with the patentability of microorganisms, the implications are clear for both the question of the patentability of other living organisms, as well as the outer limits of patentable subject matter in general. It is also clear from those decisions that the controversy is not going to go away on its own. Ultimately, Congress will have to articulate clearer guidelines as to what constitutes patentable subject matter, be it living or non-living.

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*biological Transformations—An International Problem*, 42 J. PATT. OFF. Soc'y 830, 833-38 (1960), which notes the difficulty of producing known fermentation products utilizing a new species of microorganism often vaguely described in the patent specification.