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# What Hath (Not) Chakrabarty Wrought: From the Mouse that Roared to Hello Dolly and Beyond

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# Foreword

## WHAT HATH (NOT) *CHAKRABARTY* WROUGHT: FROM THE MOUSE THAT ROARED TO HELLO DOLLY AND BEYOND

GERI J. YONOVER\*



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### I. INTRODUCTION

It did not all start with Dr. Ananda Chakrabarty.<sup>1</sup> Maybe Narcissus is to blame or to be commended for falling in love with his own image as he peered

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1. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding, in a 5-4 decision, that patent protection is afforded to an inventor who, by the process of genetic engineering, produces a living organism). See *infra* notes 8-17, 33-47 and accompanying text.

into the quiet waters of some mythological pond. Or maybe Woody Allen started the genetic ball rolling when in the movie *Sleeper*<sup>2</sup> he depicted a character cloned from a nose. Perhaps we can trace the cloning concept back even further; after all, Eve was fashioned (read "cloned") from Adam's rib. Consider too the fascination provoked by twins throughout recorded history. Literary uses of the Doppelganger phenomenon abound—from Joseph Conrad to Shakespeare to the unlikely pairing of Arnold Schwarzenegger and Danny DeVito as *Twins*<sup>3</sup> in a recent film. Human fascination with twinning, the creation of life (i.e., Frankenstein), and immortality is a constant; virtually all civilizations have created stories and adopted beliefs that explain the presence of life on this planet. But this ongoing fascination is but one piece of the cloning picture.

The other factor that sets the stage for the world-wide cloning debate, and for the articles in this issue which participate in this debate, is the sea-change in science that has occurred in this century. This change is two-fold: technological and philosophical. One part encompasses the dramatic leap in technological and biological research and knowledge which is both spectacular and swift. At times, scientific knowledge appears to be like the proverbial rolling stone, gathering speed as it hurtles down the mountainside. It is almost hard to believe that genetic science is such a relatively young discipline. Gregor Mendel worked at the turn of the twentieth century, and James Watson and Francis Crick discovered deoxyribonucleic acid (DNA sequencing) only forty-five years ago.<sup>4</sup> From the basis of Mendelian genetics, we have mastered some of the tools for the creation of life forms in less than a century. Dolly, the (allegedly) cloned sheep, is progeny of this cataclysmic scientific breakthrough in biotechnology.

The second part of the scientific revolution that lies at the core of the cloning issue is based upon changes in the way scientists and lay persons alike view science. Until rather recently, the predominant role of science was thought to be one of analysis and observation. The periodic chart of chemical elements, the listing of flora and fauna species, the mathematical formulae of Kepler, Newton, and Einstein—all reflect a *zeitgeist* of science as detached from human affairs. For good or, some say, for ill, that view of science has been displaced significantly by a view that regards science as a tool to improve our lives. And it has done so to a great extent. Science has, for example, given us antibiotics to fight a wide range of bacterial infections and cancer treatments that can, occasionally, cure or ameliorate that disease. Science has virtually eradicated polio, measles, diphtheria, tetanus, and other potentially fatal diseases.

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2. SLEEPER (Jack Rollins & Charles H. Joffe Productions 1973).

3. TWINS (Universal City Studios, Inc. 1988).

4. See DESMOND S. T. NICHOLL, AN INTRODUCTION TO GENETIC ENGINEERING 3 (1994).

The current view of science, that it is a means to improve and extend our lives, also raises exquisitely sensitive moral, philosophical, and theological questions about such issues as manipulating genes, prolonging human life, reproductive technology, parenting (whose baby is it in an *in vitro* fertilization or surrogacy situation?) and abortion. Of course, cloning is also among the issues that provoke these searching moral, philosophical, and theological questions. This Symposium Issue on cloning brings together, under one cover, articles written by experts in ethics, law, philosophy, and theology. Together, the legal perspectives<sup>5</sup> and the religious, philosophical, and ethical perspectives<sup>6</sup>

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5. See, in addition to this foreword, Robert F. Blomquist, *Cloning Endangered Animal Species?*, 32 VAL. U. L. REV. 383 (1998) (extending the cloning debate to the prospect of using cloning technology to reproduce endangered animal species and discussing public policy implications); Catharine Cookson, *Of Monsters Unleashed: A Modest Beginning to a Casuistry of Cloning*, 32 VAL. U. L. REV. 419 (1998) (utilizing the process of casuistry (i.e., analogies and paradigms) to advance the public debate over the ethics of cloning beyond the emotional level); John Finnis, *Public Reason, Abortion, and Cloning*, 32 VAL. U. L. REV. 361 (1998) (criticizing John Rawls's theory of public reason, presenting his own theory of public reason, and applying this theory to the issues of abortion and cloning); Heidi Forster & Emily Ramsey, *Legal Responses to the Potential Cloning of Human Beings*, 32 VAL. U. L. REV. 433 (1998) (reviewing state and federal legislative activities and international initiatives regarding human cloning and discussing the constitutional issues important to the human cloning debate); Clarke D. Forsythe, *Human Cloning and the Constitution*, 32 VAL. U. L. REV. 469 (1998) (discussing the status of the pre-implantation embryo, analyzing the limits of procreative liberty, and evaluating the constitutional implications of human cloning); Michael J. McDaniel, Note, *Regulation of Human Cloning: Implication for Biotechnological Advancement*, 32 VAL. U. L. REV. 543 (1998) (surveying scientific discoveries in mammalian asexual reproduction, possible animal and human applications of cloning technology, and moral and ethical objections to the use of cloning technology to produce humans, and analyzing governmental reactions in France, the United Kingdom, and the United States to the prospect of human cloning); Robert C.L. Moffat, *Cloning Freedom: Criminalization or Empowerment in Reproductive Policy?*, 32 VAL. U. L. REV. 583 (1998) (evaluating the magnitude of the threat caused by cloning technology, whether prompt, drastic political action is necessary, the legitimacy of the justifications offered for restricting the freedom to clone through criminal sanctions, the claimed benefits and costs entailed in criminalizing cloning, and the reasons for expanding rather than restricting scientific freedom).

6. See Courtney S. Campbell, *Resistance and Meaning: Religious Communities and Human Cloning*, 32 VAL. U. L. REV. 607 (1998) (examining and critiquing the religious values and the theological arguments on cloning human beings presented to the National Bioethics Advisory Commission (NBAC) and in the scholarly literature, surveying religious ethical reflection on the cloning of humans, and noting particularly the themes of "resistance" and "meaning" found in religious traditions that define the moral role of religious communities in a liberal democratic society); Daniel R. Heimbach, *Cloning Humans: Dangerous, Unjustifiable, and Genuinely Immoral*, 32 VAL. U. L. REV. 633 (1998) (explicating the dangers of cloning human life, noting particularly the health, socio-political, and moral risks, analyzing whether the benefits to be gained from human cloning outweigh the attendant risks, and arguing, on various grounds, that cloning human life is an immoral project); Jan C. Heller, *Religious Perspectives on Human Cloning: Revisiting Safety as a Moral Constraint*, 32 VAL. U. L. REV. 661 (1998) (considering the moral constraint of safety as used to construct moral arguments for or against human cloning as it is applied to the "potential child" and arguing that safety cannot be coherently used as a moral constraint); Leon R. Kass, *The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans*, 32 VAL. U. L. REV. 679

offered in this Issue participate in the public debate over cloning, but they also lay some of the groundwork necessary for the state and federal legislative activities currently underway and the case law that is sure to develop. These various perspectives will inform both law and public policy and address many of the concerns underlying the cloning debate.

## II. ENTER DR. CHAKRABARTY

So, given our centuries-old fascination with the creation of life, especially twinning, and the two-prong change—technological and philosophical—in science itself, perhaps Dolly the sheep and the current debate about human cloning<sup>7</sup> would have occurred even if Dr. Chakrabarty had not invented and patented an

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(1998) (analyzing the implications that human cloning technology would have for human reproduction, criticizing the report and recommendations of the NBAC, and arguing for a ban on the cloning of humans); Gilbert Meilaender, *Cloning in Protestant Perspective*, 32 VAL. U. L. REV. 707 (1998) (providing a Protestant analysis of human cloning, distinguishing between the making and the begetting of a child, and noting that the meaning of a child limits human freedom to make and remake ourselves); James L. Nelson, *Cloning, Families, and the Reproduction of Persons*, 32 VAL. U. L. REV. 715 (1998) (discussing how including cloning as a reproductive option might affect family structures and the social tasks involved in reproducing persons); Kenneth D. Pimple, *The Ethics of Human Cloning and the Fate of Science in a Democratic Society*, 32 VAL. U. L. REV. 727 (1998) (agreeing with the NBAC's conclusion that a moratorium on human cloning research is warranted, analyzing the instrumental concerns raised in secular objections to human cloning, and discussing concerns that our populace may not have the ability to engage in meaningful debate over the morality of many forms of scientific research); Kurt A. Richardson, *Human Reproduction by Cloning in Theological Perspective*, 32 VAL. U. L. REV. 739 (1998) (analyzing science and the project of human cloning from a theological perspective and discussing the implications of the Christian doctrine that human beings are created by God, bearing his image, and are intended by God to develop in the context of a natural, father-mother family situation); Maura A. Ryan, *Cloning, Genetic Engineering, and the Limits of Procreative Liberty*, 32 VAL. U. L. REV. 753 (1998) (analyzing the moral issues that underlie claims for a right to procreate, criticizing the liberal rights position on procreative liberty, as defended by John A. Robertson, and arguing that a proper understanding of reproductive responsibility requires drawing upon deep religious, cultural, and moral traditions); Thomas A. Shannon, *Human Cloning: Religious and Ethical Issues*, 32 VAL. U. L. REV. 773 (1998) (discussing the religious themes of playing God and of the image of God in humans as they relate to the cloning debate, the status of the pre-implantation embryo, and the various moral aspects of cloning scenarios, and providing public policy proposals).

7. In addition to the articles appearing in this Symposium issue, see IRA H. CARMEN, *CLONING AND THE CONSTITUTION: AN INQUIRY INTO GOVERNMENTAL POLICYMAKING AND GENETIC EXPERIMENTATION* (1985); Michael Broyde, *Cloning People: A Jewish Law Analysis of the Issues*, 30 CONN. L. REV. 503 (1998); John A. Maher, *What of the Brave New World?*, 3 DICK. J. ENVTL. L. & POL'Y. 1 (1994); Stephen A. Newman, *Human Cloning and the Family: Reflections on Cloning Existing Children*, 13 N.Y. L. SCH. J. HUM. RTS. 523 (1997); George P. Smith II, *Pathways to Immortality in the New Millennium: Human Responsibility, Theological Direction, or Legal Mandate*, 15 ST. LOUIS U. PUB. L. REV. 447 (1996); Mona S. Amer, Comment, *Breaking the Mold: Human Embryo Cloning and Its Implications for a Right to Individuality*, 43 U.C.L.A. L. REV. 1659 (1996).

oil-eating bug.<sup>8</sup> But, at least, the *Chakrabarty* decision helped pave the way. At the time *Chakrabarty* percolated through the Patent Office and up to the Supreme Court, it was regarded as a watershed case. The ensuing eighteen years have only added to its landmark luster. The rest of this Article will describe how *Chakrabarty* set the stage for today's raging debate on cloning.

Sometime in the 1960s and early 1970s, Ananda Chakrabarty, a microbiologist, invented "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degenerative pathway."<sup>9</sup> In short, Chakrabarty had invented an oil-eating bug. This bug had never before existed in this form in nature until Chakrabarty transferred, by the process of genetic engineering, certain plasmids (hereditary material) that can degrade camphor and octane, two components of crude oil, into a single *pseudomonas* bacterium.<sup>10</sup> Without such transplantation, a *Pseudomonas* bacterium cannot degrade oil.<sup>11</sup> The breakthrough nature of this invention was to foster "more efficient and rapid oil-spill control,"<sup>12</sup> a cure for one of the more modern, human-caused "plagues" that we face every few years.<sup>13</sup>

Chakrabarty's patent application consisted of three categories of claims: (1) the process claim for the method of bacteria production; (2) claims for an inoculum of carrier material (e.g., straw to float on water with the bacteria) and the plasmid-injected *Pseudomonas*; and (3) the *Pseudomonas* itself.<sup>14</sup> While allowing the first two claims, the patent examiner rejected the claim for the bacteria itself because "(1) . . . micro-organisms are 'products of nature,' and (2) . . . living things . . . are not patentable subject matter" under [the Patent Act].<sup>15</sup>

After an unsuccessful administrative appeal, a successful appeal to the Court of Customs and Patent Appeals (CCPA),<sup>16</sup> a grant of *certiorari*, a

8. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

9. *Id.* at 305 (footnote omitted) (the Court is ostensibly referring to Chakrabarty's patent application).

10. *Id.* at 305, n.1.

11. *Id.*

12. *Id.* at 305, n.2.

13. Consider, for example, the 1989 Exxon Valdez spill in Alaska and the 1978 Amoco Cadiz debacle off the French coast.

14. *Diamond v. Chakrabarty*, 447 U.S. 303, 305-06 (1980).

15. *Id.* at 306.

16. *Application of Chakrabarty*, 596 F.2d 952 (C.C.P.A. 1979). The CCPA was the predecessor court of the Federal Circuit which Congress created in 1982. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982). The Federal Circuit has exclusive jurisdiction over all patent appeals. Its creation served to eliminate the significant disparity in patent decisions among the regional courts of appeals. See generally Rochelle Cooper Dreyfuss,

vacating of the court's decision, and CCPA reaffirmance of allowances after the remand, the Supreme Court again granted *certiorari* and, over the dissent of Justices Brennan, White, Marshall, and Powell, held that organisms produced by genetic engineering are not excluded from patent protection.<sup>17</sup> To underscore the landmark status of this decision, the ensuing discussion will first briefly review the Patent Act.<sup>18</sup> The discussion will then shift back to an analysis of the Court's decision and reflection on its contribution to the current cloning debate.

### III. THE PATENT ACT

The Patent Act of 1952, with significant amendments to date, can trace its lineage to the first federal patent law in 1790<sup>19</sup> and further back to England and Venice. The earliest known patent protection scheme for useful inventions, such as a water-raising mechanism, was Venetian and dates from the mid-fifteenth century.<sup>20</sup> England borrowed the Venetian approach and its Statute of Monopolies permitted the Crown to grant patents for a maximum term of fourteen years to a "true and first inventor."<sup>21</sup> The fourteen-year term was not altogether arbitrary; it represented twice the apprentice term for one learning a trade. At the time Dr. Chakrabarty sought patent protection, the duration was seventeen years.<sup>22</sup> Recently, patent protection has been changed to a general twenty-year term from the date of application and begins when the patent issues.<sup>23</sup>

Congressional authority to award what essentially is a monopoly—giving the patent holder the right to exclude others from, *inter alia*, making, using, or selling the patented invention during the patent term—emanates from Article I of the U.S. Constitution: "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."<sup>24</sup> The Patent Act, it is thought, fosters the "Progress of . . .

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*The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989).

17. *Chakrabarty*, 447 U.S. at 318.

18. 35 U.S.C. § 31-376 (1994).

19. Act of April 10, 1790, Ch. 7, 1 Stat. 109-110.

20. BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 21 (1967). Several famous Americans relied on the patent system for protection. Before he became President, Abraham Lincoln himself obtained a patent for a device to free boats from shoals. Patent No. 6469. Thomas Edison is one of the most prolific inventors; his patents number more than one thousand. Kerin Kelly, Comment, *The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?*, 24 J. MARSHALL L. REV. 263, 297 (1990).

21. 21 Jam. 1, c. 3 (1624).

22. 35 U.S.C. § 154 (1976).

23. 35 U.S.C. § 154 (1994).

24. U.S. CONST. art. I, § 8, cl. 8. Copyright authorization is contained in the same clause.

useful Arts” by establishing a quid pro quo system. If I, the inventor, disclose my invention to the public by applying for a patent which results in issuance,<sup>25</sup> then, in exchange for such disclosure, I receive a monopoly on that invention for a term of years. At the end of the patent term, anyone may have full access to that invention, and, during the term, anyone can use the information contained in my patent, provided that such use does not infringe upon my patented invention. Professor Goldstein describes the way in which the Patent Act serves its constitutional mandate:

First, a patent system provides an incentive to invent by offering the possibility of reward to the inventor and to those who support him. This prospect encourages the expenditure of time and private risk capital in research and development efforts.

Second, and complementary to the first, a patent system stimulates the investment of additional capital needed for the further development and marketing of the invention. In return, the patent owner is given the right, for a limited period, to exclude others from making, using, or selling the invented product or process.

Third, by affording protection, a patent system encourages early public disclosure of technological information, some of which might otherwise be kept secret. Early disclosure reduces the likelihood of duplication of effort by others and provides a basis for further advances in the technology involved.

Fourth, a patent system promotes the beneficial exchange of products, services, and technological information across national boundaries by providing protection for industrial property of foreign nationals.<sup>26</sup>

Thus, when the Supreme Court held that Chakrabarty could obtain a patent for his claims to a genetically-altered *Pseudomonas* the “Progress of . . . useful Arts” arguably was furthered.

It is important to note, however, that an inventor has to surmount several very high hurdles in order to obtain patent protection: the invention has to be

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25. By law, all applications are kept confidential until issuance. 35 U.S.C. § 122 (1994).

26. PAUL GOLDSTEIN, *COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES* 16 (4th ed. 1997).



nonobvious,<sup>27</sup> novel,<sup>28</sup> not time-barred in its application,<sup>29</sup> fully disclosed in its application,<sup>30</sup> and useful, patentable subject matter.<sup>31</sup> The latter requirement posed the issue to be resolved in *Chakrabarty*: “whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.”<sup>32</sup>

#### IV. THE *CHAKRABARTY* HOLDING—LIVING ORGANISMS ARE PATENTABLE

The primary distinction between the majority and the dissent turns on the patentability of living matter. The same government that in 1995 received, as assignee, a patent on a bloodcell line taken from a Papua, New Guinea tribesman<sup>33</sup> had argued in *Chakrabarty* that life forms were not patentable.

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27. 35 U.S.C. § 103(a) (1994). In *Graham v. John Deere Co.*, the Court established a three-part test for determining nonobviousness:

[T]he scope and content of the prior [relevant] art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. . . . [Additionally,] [s]uch secondary considerations as commercial success, long felt but unresolved needs, failure of others, . . . might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

383 U.S. 1, 17-18 (1966).

The Federal Circuit has elevated these “secondary considerations” to equal importance with the primary three-part *Deere* test. See, e.g., *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

28. 35 U.S.C. § 102(a) (1994). To establish lack of novelty in the sense of “anticipation,” “a single prior art reference [must] disclose [] each and every element of the claimed invention,” *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715-16 (Fed. Cir. 1984), and constitute a “disclosure sufficient to enable one skilled in the art to reduce the disclosed invention to practice.” *Application of Borst*, 345 F.2d 851, 854 (C.C.P.A. 1965), cert. denied, 382 U.S. 973 (1966) (emphasis in original).

29. 35 U.S.C. § 102(b) (1994). An applicant has a twelve-month grace period to apply for a patent after the invention’s disclosure, by the inventor or others, to the public. Time devoted to experimental use by the inventor is excluded. See *T.P. Lab., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir.), cert. denied, 469 U.S. 826 (1984).

30. 35 U.S.C. § 112 (1994). The specifications must describe the invention in an objective manner so that a person skilled in the art of the invention (i.e., a biotechnologist in the *Chakrabarty* context) can make or use it. The Act also requires the inventor to describe the “best mode” the inventor subjectively believes of “carrying out his [or her] invention.” *Id.*

31. 35 U.S.C. § 101 (1994). Even if the patent examiner agrees that the applicant has comported with all the requirements of patentability and, despite the presumption of validity that an issued patent carries, 35 U.S.C. § 282 states that when sued for infringement in a federal district court, an infringer can attack the validity of a patent on any of the grounds mentioned above. See *supra* notes 27-30 and accompanying text. Federal jurisdiction over patent cases is exclusive. 28 U.S.C. § 1338(a) (1994).

32. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

33. Patent No. 5,397,696 was assigned to the Department of Health and Human Services by five “inventors,” including four U.S. government researchers and a medical anthropologist at the Institute of Medical Research, Papua, New Guinea. Recently, the government formally abandoned

First, according to the government, the Plant Patent Act<sup>34</sup> and the 1990 Plant Variety Protection Act<sup>35</sup> indicate that Congress believed that, as a general proposition, living things were not patentable,<sup>36</sup> thus, the need for these two pieces of legislation. The majority rejected this characterization, finding instead “that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.”<sup>37</sup> Although original *Pseudomonas* itself was a product of nature, the introduction into the bacteria of new genetic material capable of degrading oil constituted an invention of man. Second, the government posited that micro-organisms did not qualify as patentable subject matter without express congressional authorization—which Congress had not given. Indeed, genetic technology was absent and “unforeseen when Congress enacted § 101.”<sup>38</sup> The majority disposed of this argument by countering that the broad statutory language of the Patent Act was unambiguous and designed to serve the constitutional goal of promoting the “useful Arts.”<sup>39</sup>

The further arguments by the government and *amici curiae* rested primarily on policy considerations which focused on the “grave risks” of genetic research that, they feared, could lead to pollution, disease, loss of genetic diversity, and depreciation of the value of human life.<sup>40</sup> (Note that some, if not all, of these concerns underlie the cloning debate as well.) The majority turned a deaf ear, believing that it was for Congress, not the Court, to consider such policy matters.<sup>41</sup> Further, the Court mentioned, somewhat disingenuously, that “[t]he grant or denial of patents on micro-organisms is not likely to put an end to genetic research or . . . its . . . risks.”<sup>42</sup> This cannot be true. Insofar as Congress enacted the patent laws to serve the constitutional goal of promoting the useful arts and those laws do in fact encourage innovation through monopoly protection,<sup>43</sup> the grant of such protection will increase genetic research. In fact, post-*Chakrabarty*, this is exactly what happened. Patent protection has

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this patent presumably because of the controversy concerning what some have called “biopiracy.” *NIH Abandons HTLV-Z Patent*, 10 ANTIVIRAL AGENTS BULL., Apr. 1, 1997, available in 1997 WL 9577558.

34. 35 U.S.C. §§ 161-164 (1994). The Plant Patent Act permits patenting of certain asexually reproduced plants. *Id.* at § 161.

35. 7 U.S.C. § 2402(a) (1994). This Act allows patenting of certain sexually reproduced plants, but excludes bacteria. *Id.*

36. *Chakrabarty*, 447 U.S. at 311.

37. *Id.* at 313.

38. *Id.* at 314.

39. *Id.* at 315.

40. *Id.* at 316.

41. *Id.* at 317.

42. *Chakrabarty*, 447 U.S. at 317.

43. See GOLDSTEIN, *supra* note 26.

moved up the animal chain from Dr. Chakrabarty's bug to an oyster,<sup>44</sup> to a mouse,<sup>45</sup> and, finally, to human DNA sequencing.<sup>46</sup> The *Chakrabarty* majority was prescient in its view that "anything under the sun that is made by man"<sup>47</sup> is includable as patentable subject matter in section 101 of the Patent Act.

#### V. THE IMPACT OF *CHAKRABARTY*

Genetic engineering did not start with Dr. Chakrabarty. Humans have been experimenting with the gene pool of animals for many hundreds of years by selective cross-breeding and, more recently, artificial insemination. Yet, as this Article has noted, the availability of patent protection spurs research and development.<sup>48</sup> Patents have the ability, if they cover a successful drug, a better mousetrap, a more efficient vacuum cleaner, or a bloodcell line,<sup>49</sup> to create tremendous financial potential during the patent term. Recall that the patent owner can prevent infringement by excluding others from making, using, or selling the patented invention for twenty years.<sup>50</sup> Infringement of a successful patent can be extremely costly. In 1991, Polaroid received over \$800 million in damages in a bench trial in which it charged Kodak with infringement.<sup>51</sup> Hughes Aircraft received over \$100 million in damages against the United States.<sup>52</sup> Infringement can be literal: the infringing device reads

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44. *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (P.T.O. Bd. Pat. App. & Interf. 1987), *aff'd on other grounds*, 846 F.2d 77 (Fed. Cir. 1988). To make oysters suitable for year-round consumption (the old "R" month adage, apparently, is scientifically correct), the genetic material of polyploid oysters was manipulated.

45. Patent No. 4,736,866 covered a mouse with a genetic alterations affecting its ability to develop cancerous tumors quickly. (The Patent Office issued the mouse patent after the expiration of a voluntary eight-month moratorium on animal patents.)

46. Almost 1200 patents on human DNA were issued worldwide between 1981 and 1995. S. M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 387 (1996). *See also supra* note 33.

47. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 1979, 82d Cong. 5 (1952); H.R. Rep. No. 1923, 82d Cong. 6 (1952)).

48. *See supra* note 46 and accompanying text.

49. *See supra* note 33 and accompanying text.

50. 35 U.S.C. § 271 (1994).

51. *Polaroid Corp. v. Eastman Kodak Co.*, No. 76-1634-MA, 1991 WL 4087, at \*5 (D. Mass. Jan. 11, 1991).

52. *Hughes Aircraft Co. v. U.S.*, 31 Fed. Cl. 481 (1994).

exactly on the patented invention.<sup>53</sup> This type of infringement is infrequent. Far more common is infringement under the Doctrine of Equivalents which asks whether the infringing device “performs substantially the same function in substantially the same way to obtain the same result.”<sup>54</sup>

Remedies for infringement (whether the infringement is literal or equivalent) are significant. They include injunctions,<sup>55</sup> damages (possibly trebled) or a reasonable royalty,<sup>56</sup> and reasonable attorneys’ fees in “exceptional cases.”<sup>57</sup> Additionally, if certain other unpatented or patented (but not infringed) devices are usually sold as part of a package that includes the patented invention, then the “entire market value rule” will include, as damages, profits on the unpatented (or patented but not infringed) components.<sup>58</sup> Such is the power of a patent monopoly.

In short, although limited in duration, a patent monopoly means big bucks—to use the vernacular. Insofar as Dr. Chakrabarty was able to patent his altered *Pseudomonas*, the potential arose for great financial rewards. Ironically, in his case, this did not occur. Even though he was able to demonstrate to the Patent Office the utility of his oil-eating bug, he struggled with getting approval to release these oil-hungry microbes into the environment.<sup>59</sup> Apparently, as of 1990, General Electric, the assignee of Chakrabarty’s patent, could not envision making enough profits to pay for the costs in money and time for patent approval.<sup>60</sup>

Nevertheless, the seminal decision in *Chakrabarty*—life is patentable—stands. The repercussions of that 1980 decision abound.<sup>61</sup> *Chakrabarty* foreshadowed tremendous advances in biotechnology and cataclysmic changes in the views of the Patent Office, the courts, scientists, and all of us about the nature of life on this planet. The cloning debate, which focuses on the potential of cloning for good and, perhaps, for evil, is a logical

53. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 607 (1950).

54. *Graver*, 339 U.S. at 608 (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)). Recently, the Supreme Court affirmed the availability of the Doctrine of Equivalents in certain non-literal infringement situations. See *Hilton-Davis Co. v. Warner-Jenkinson Co.*, 117 S. Ct. 1040 (1997).

55. 35 U.S.C. § 283 (1994).

56. 35 U.S.C. § 284 (1994).

57. 35 U.S.C. § 285 (1994).

58. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549 (Fed. Cir.) (citing *Paper Converting Mach. Co. v. Magna-Graphics Corp.* 745 F.2d 11, 23 (Fed. Cir. 1984)), cert. denied, 116 S. Ct. 184 (1995).

59. Jon Van, *Professor out to Oil-Proof Beaches*, CHI. TRIB., June 14, 1990, at 1.

60. *Id.* at 2.

61. For example, U.S. Patent No. 4,237,224 covers a method of DNA cloning in bacteria. U.S. Patent No. 4,339,216 covers a method of DNA cloning in animal cells.

heir of the 1980 decision in *Chakrabarty*. Despite serious recommendations that would prohibit federal and state funding of human cloning,<sup>62</sup> science marches on, and public opinion can shift: “Yesterday’s [n]ever [may be] [t]oday’s why not. . . .”<sup>63</sup>

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62. See NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 107-10 (1997).

63. Gina Kolata, *On Cloning Humans, ‘Never’ Turns Swiftly into ‘Why Not,’* N.Y. TIMES, Dec. 2, 1997, at A1.