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# MONSTERS AT THE PATENT OFFICE: THE INCONSISTENT CONCLUSIONS OF MORAL UTILITY AND THE CONTROVERSY OF HUMAN CLONING

## INTRODUCTION

There are monsters loose in the United States patent system. Human clones, part-man, part-beast creations, and gentle-sounding, but bizarre inventions that “encompass a human” are wreaking havoc in the halls of Congress and at the United States Patent and Trademark Office. But are these man-made creatures truly a “parade of horrors”<sup>1</sup> as the United States Supreme Court once put it—the inevitable slippery slope of the United States’ extraordinary advances in the biotech industry? Or do they represent something totally benign that, given the goals of our patent system, will “silently sink into contempt and disregard”<sup>2</sup> as a forgotten baby step toward something enormously valuable to science? The issues confronting this clash of law and science may have colossal implications not only on one of the American economy’s fastest growing sectors, but perhaps on our definition of what is or is not human and what constitutes life itself.<sup>3</sup> Some authors suggest that patenting such technologies will lead to the commodification of humans and envision an Aldous Huxley-esque

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1. *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980). The Court noted that the petitioner’s amicus briefs pointed to the potential for “grave risks” that may be associated with further exploration of genetic manipulation. *Id.* In validating a patent directed to the product of a genetic manipulation process, the Court dismissed the concerns that suggested that “genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time . . .” *Id.* The Court also stated that:

We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better “to bear those ills we have than fly to others that we know not of.”

*Id.*

2. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

3. See Dashka Slater, *huMouse*, 1 LEGAL AFF. 20, 28 (2002) (noting that, should the cloning debate regarding patents reach the Supreme Court, and the justices take up the ontological issues passed up in *Chakrabarty*, “the Court presumably would have to face the question that has puzzled the patent office for decades and philosophers for eons: What makes us human? Are we human because of what we do and what we are capable of, or because of something written in our DNA?”); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247 (2000).

“brave new world” where humanity is given a dollar value and parents may choose their children’s traits as if selecting a meal from a buffet.<sup>4</sup> Others see cloning and associated technologies as the destiny of medical science that could lead to the complete eradication of all human ills.<sup>5</sup>

Progress, however, does not come without a price, and an issued patent allowing the legal right to exclude others from valuable techniques resulting from costly research is nearly essential to industrial and economic success.<sup>6</sup> As the biotech industry applies more of its technology to curing human ills, the issued patents claiming the products of these techniques come closer to granting an exclusive, though limited, property right in a human being.<sup>7</sup> To contend with the tremendous ethical issues challenging traditional legal notions within the patent system, the United States Patent and Trademark Office (USPTO) resurrected a monster of its own: moral utility. The concept comes from an 1817 decision defining a patentable invention as one

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4. See generally ALDOUS HUXLEY, *BRAVE NEW WORLD* (1932); Ruth Hubbard & Stuart Newman, *Yuppie Eugenics*, Council for Responsible Genetics, available at <http://www.zmag.org/ZMag/articles/march02hubbard-newman.htm> (last visited Nov. 2, 2003). The Hubbard and Newman article noted that recent advances in marketing human genetic manipulation lead to the conclusion that:

[W]e have entered the era of Yuppie Eugenics. A contemporary, ostensibly voluntary form of older ideas and practices, Yuppie Eugenics is based in modern molecular genetics and concepts of “choice,” and has begun to raise the high tech prospect of employing prenatal genetic engineering. What it shares with the earlier doctrines is the goal of improving and perfecting human bloodlines and the human species as a whole.

*Id.*

5. See generally *Human Cloning: Must We Sacrifice Medical Research in the Name of a Total Ban?: Hearing on S. 1899 Before the Senate Judiciary Comm.*, 107th Cong. 20-25 (2002) (statement of Dr. Irving L. Weissman, Chair, Panel on Scientific and Medical Aspects of Human Cloning, The National Academy of Sciences, and Professor, Stanford University School of Medicine), available at <http://judiciary.senate.gov/testimony.cfm> (last visited Nov. 2, 2003). Dr. Weissman stated that:

Scientists place high value on the freedom of inquiry—a freedom that underlies all forms of scientific and medical research. Recommending restriction of research is a serious matter, and the reasons for such a restriction must be compelling. In the case of human reproductive cloning, we are convinced that the potential dangers to the implanted fetus, to the newborn, and to the woman carrying the fetus constitute just such compelling reasons. In contrast, there are no scientific or medical reasons to ban nuclear transplantation to produce stem cells, and such a ban would certainly close avenues of promising scientific and medical research.

*Id.*

6. See generally Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

7. Any patent claiming the product of human genetic manipulation would confer on the owner the limited right to exclude others from using or practicing that invention. See generally ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 48 (3d ed. 2002) (stating that the rights conferred by a patent are limited to “the right to exclude and nothing else”).

that was, among other things, not “injurious to the well-being, good policy, or sound morals of society.”<sup>8</sup> Courts have applied moral utility inconsistently and sporadically at best,<sup>9</sup> and a recent decision might have severely weakened the ability of the USPTO to apply the concept to deny patents directed to humans.<sup>10</sup>

In 1999, the Federal Circuit Court of Appeals held in *Juicy Whip v. Orange Bang*<sup>11</sup> that a district court erred when it invalidated Juicy Whip’s patent entitled “Post-Mix Beverage Dispenser With an Associated Simulated Display of Beverage.”<sup>12</sup> In reversing the decision, the Federal Circuit Court of Appeals stated that the lower court erred in holding that Juicy Whip’s patent was invalid for lack of utility “on the ground that the patented invention was designed to deceive customers by imitating another product and thereby increasing sales of the particular good.”<sup>13</sup> The court reasoned that the doctrine of moral or beneficial utility—that inventions “injurious to the well-being, good policy, or sound morals of society” are unpatentable—“has not been applied broadly in recent years.”<sup>14</sup> The court’s reversal, however, did not go so far as to refuse to ever uphold the reasoning. Rather, the court left some room for the idea that moral utility might have some further application to modern patent law and held only that inventions cannot “be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.”<sup>15</sup>

But exactly how far is the Federal Circuit Court of Appeals willing to take the idea of moral utility? The *Juicy Whip* holding severely limits the doctrine as applied to mechanical devices.<sup>16</sup> However, the court’s refusal to invalidate the idea of moral utility altogether might signal that the doctrine could be applied in other circumstances, or perhaps, in other patentable subject areas.

The debate surrounding the process of human cloning provides fertile ground for the court to sow moral utility into modern patent law. However, in light of *Juicy Whip* and the reluctance of most scholars and courts to accept morality as a condition within the American patent system, application of moral utility might not provide the most

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8. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817). See also *infra* note 23 and accompanying text.

9. See *infra* notes 107-128 and accompanying text.

10. See *infra* notes 37-55 and accompanying text.

11. *Juicy Whip v. Orange Bang*, 185 F.3d 1364 (Fed. Cir. 1999).

12. *Id.* at 1365.

13. *Id.*

14. *Id.* at 1366-67.

15. *Id.* at 1368.

16. See *infra* note 119 and accompanying text.

reliable legal reasoning for rejecting patents directed to the processes and products of human genetic manipulation.<sup>17</sup> Regardless of any misgivings about construing morality in patent law and, in the absence of congressional guidance to the contrary, the courts and the USPTO may find moral utility as the only tenable reasoning for rejecting these patents. This Comment will examine the development of the moral utility doctrine and evaluate the feasibility of its modern application in the United States patent system to some highly controversial aspects of biotechnology.

Part II will trace the development of the moral utility doctrine and its past applications.<sup>18</sup> Part III will discuss the current state of moral utility in light of *Juicy Whip* and examine the USPTO's reluctance to apply the doctrine as well as legislative efforts to come to terms with controversial technology.<sup>19</sup> Part IV will look at the possibility of applying moral utility within the United States patent system and the potential complications it might cause.<sup>20</sup>

## II. BACKGROUND

There is no explicit statutory basis for the moral utility requirement.<sup>21</sup> Applications of the doctrine necessarily depend on judicial and administrative interpretations of the Patent Act and relevant precedent. This section first describes the various sources that combine to create moral utility, and second provides some insight into the relevance of the doctrine to the modern cloning debate.

### A. *Moral Utility: The Constitution, the USPTO, and the Federal Courts*

There are three major bases for the concept of patentable utility: the Constitution, the administrative interpretation of the Patent Act and federal court precedent through USPTO registration, and opinions of the federal courts. Each source contributes a piece to the moral utility puzzle: the Constitution provides the basis for the patent system by protecting the useful arts;<sup>22</sup> the USPTO evaluates patent applications based on numerous criteria, including, in some instances, moral utility;<sup>23</sup> and the federal courts adjudicate claims of patent va-

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17. See *infra* notes 102-139 and accompanying text.

18. See *infra* notes 21-173 and accompanying text.

19. See *infra* notes 175-243 and accompanying text.

20. See *infra* notes 240-242 and accompanying text.

21. See *infra* notes 24-29, 56-59 and accompanying text.

22. See *infra* note 25 and accompanying text.

23. See *infra* notes 154-159 and accompanying text.

lidity based, in part, on an invention's utility.<sup>24</sup> This section explores the origin of the doctrine and describes its evolution and incorporation into modern practice under the 1952 Patent Act. Furthermore, this section illuminates the tension created by *Juicy Whip's* weakening of moral utility despite the principle's continued recognition by both scholars and the USPTO.

### 1. *The Historical Perspective of Moral Utility*

Article I, Section 8 of the United States Constitution holds the authority for the United States patent system and the basis for the utility requirement itself.<sup>25</sup> The simple clause “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” is the starting point for all United States patent law.<sup>26</sup> Thomas Jefferson's belief that “ingenuity should receive liberal encouragement” was the cornerstone for the constitutional provision and the first Patent Act.<sup>27</sup> Today, it still serves as the primary objective of the United States patent system.<sup>28</sup> Authored by Jefferson in 1790, the first United States Patent Act authorized patents for “any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter.”<sup>29</sup> By its emphasis on protection of only that which was new and useful, Jefferson's Act provided the first glimpse of the importance of utility. By the Constitutional mandate allowing Congress to “[p]romote the Progress of Science and the useful Arts” and since the first Patent Act, no patent may be granted unless the invention it describes is useful.<sup>30</sup>

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24. *Brenner v. Manson*, 383 U.S. 519, 529 (1966) (stating that “the concept of utility has maintained a central place in all our patent legislation, beginning with the first patent law in 1790 and culminating in the present . . . provision . . .”).

25. U.S. CONST. art. I, § 8, cl. 8.

26. *Id.*

27. 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed., 1871).

28. *Graham v. John Deere Co.*, 383 U.S. 1, 5-6 (1966) (stating that Article I, Section 8, Clause 8 of the Constitution was “both a grant of power and a limitation.”) The Court also stated, “This qualified authority . . . is limited to the promotion of advances in the ‘useful arts . . .’ The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose.” *Id.*

29. Act of Feb. 21, 1793, § 1, 1 Stat. 318. This law replaced the first Patent Act of 1790 and more clearly defined the scope of the grant. Although providing a first step, the statute did not begin to resemble the modern patent system until its revision in 1836. Then, a formal system of examination, with professional examiners, was enacted to bolster patent protection. *Id.*

30. U.S. CONST. art. I, § 8, cl. 8.

However, the meaning of the term “useful” within the context of the 1790 law was never defined by Congress.<sup>31</sup> In 1817, Justice Joseph Story enunciated the first interpretation of the term “useful” within the 1790 Act.<sup>32</sup> In an infringement action that contested the validity of a patent granted to the inventor of a type of pump, Justice Story rejected the argument that the plaintiff must show that his invention was “for the public, a better pump than the common pump” to be “new and useful” according to the 1790 Act.<sup>33</sup> Justice Story’s formulation of utility under the statute required that the invention be socially beneficial, that:

[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word “useful,” therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention. But if the invention steers wide of these objections, whether it be more or less usefull [sic] is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.<sup>34</sup>

Justice Story’s definition of patentable utility as not “frivolous or injurious” and as the opposite of “mischievous or immoral” was the first recognition of a beneficial or moral component to patents.<sup>35</sup> Nearly all future applications of the moral utility doctrine would cite his formulation.<sup>36</sup>

Early decisions invalidating patents for lack of moral utility based on Justice Story’s standard focused on the fact that the invention facilitated illegal or immoral acts.<sup>37</sup> The highest concentration of rejections based on moral utility concerned gambling devices.<sup>38</sup> Application of Justice Story’s formulation led judges early on to reject patents on devices that could only be used for the immoral act of gam-

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31. Act of Feb. 21, 1793, § 1. The law merely sets forth the basic requirements for patentability, that “any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter” is eligible. *Id.* at 319.

32. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

33. *Id.*

34. *Id.*

35. *Lowell*, 15 F. Cas. at 1019.

36. See generally *Nat’l Automatic Device Co. v. Lloyd*, 40 F. 89, 90 (C.C.N.D. Ill. 1889); *Cusano v. Kotler*, 159 F.2d 159, 162 (3d Cir. 1947); *In re Nelson*, 280 F.2d 172, 178-79 (C.C.P.A. 1960); *Juicy Whip*, 185 F.3d at 1366; and most recently *Geneva Pharms., Inc. v. Glaxosmithkline*, 213 F. Supp. 2d 597 (E.D. Vir. 2002).

37. See generally *Nat’l Automatic Device Co.*, 40 F. at 90; *Schultze v. Holtz*, 82 F. 448, 449 (C.C.N.D. Cal. 1897).

38. See cases cited *supra* note 37.

bling.<sup>39</sup> For example, in *National Automatic Device Co. v. Lloyd*,<sup>40</sup> the court held that the patent for a “Toy Automatic Race-Course” commonly employed in bars and used only as a gambling device was unpatentable because “it [was] not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful.”<sup>41</sup> However, early application of the doctrine led to abuse as several courts invalidated patents that had potentially significant uses outside their primary uses in gambling.<sup>42</sup>

As courts and scholars tried to clarify the limits of utility, the focus began to shift from morality to the idea that the invention must confer some benefit on the public.<sup>43</sup> An illegal or immoral utility for an invention was described as the absence of public benefit and “destitute of true utility.”<sup>44</sup> Even where the invention’s product was socially beneficial, if the net result of the invention’s use was detrimental to society, it lacked patentable utility.<sup>45</sup> One opinion written at the beginning of the twentieth century hinted at the course the courts would

39. *Id.*

40. 40 F. 89.

41. *Id.* at 90.

42. *Schultze*, 82 F. at 449 (holding a patent for a coin-operated device invalid where the inventor’s claimed utility was “the telling of a fortune, which may be effected by means of a prepared list of statements” by the conclusory declaration that “[t]here is certainly no utility apparent in this device”).

43. 1 WILLIAM C. ROBINSON, *LAW OF PATENTS FOR USEFUL INVENTIONS* § 338 (1890) (recognizing that “[i]n order that an invention may be patentable it must not only be bestowed upon the public by its inventor, but when bestowed it must confer on them a benefit”).

44. *Id.* § 340. Robinson stated that:

Inventions which accomplish definite practical results may nevertheless possess such attributes as destroy the benefits that otherwise they would bestow upon the public. Inventions whose chief or only value resides in the facilities which they afford to men to perpetuate some wrongful injury either by fraud or violence against each other are thus regarded as destitute of true utility.

*Id.*

45. *Mitchell v. Tilghman*, 86 U.S. 287, 396-97 (1873). The Court held that an erratic or dangerous invention was invalid for lack of utility because:

[E]ven where the means described will accomplish the described result, . . . it cannot be held that the invention is useful if it appears that the operator, [sic] in using the described means, is constantly exposed to imminent danger, either from the explosive tendency of the substance to be used or from the liability of the vessel to burst which is required to be employed as means of accomplishing the patented result. Where the patentee finds it necessary to employ any such dangerous means to accomplish the described end it cannot be held that his invention is useful, within the meaning of the patent law, even though it appears that the operator, when no such disaster happens, may be able to work out the described result by the described means, as it is quite clear that Congress, in making provision to secure to inventors the exclusive right to their discoveries, never intended to promote any such as were in their nature constantly dangerous to the operator in employing the described means to accomplish the described result.

*Id.*



eventually take regarding the proper role for morality within patentable utility.<sup>46</sup> In *Fuller v. Berger*, the United States Court of Appeals for the Seventh Circuit formulated a test for patentable utility that stated "everything [is] useful within the meaning of the law, if it is used (or is designed and adapted to be used) to accomplish a good result, though in fact it is oftener used . . . to accomplish a bad one."<sup>47</sup> Furthermore, even if only the present uses for the invention were illegal or immoral, if "the court itself should see, or be convinced by experts" that there were acceptable uses for the device, then its utility should be upheld.<sup>48</sup>

The *Fuller* court stated that the proper gauge of utility should be any measure of benefit conferred upon society and that judges, despite personal reservations about the morality of an invention's use, were not the proper arbiters of such a standard.<sup>49</sup> In upholding the patent for an invention that detected bogus coins in gambling machines, the court concluded that:

It is obvious that a denial of the [patent] would leave the defendants and others perfectly free, so far as the power of this court is concerned, to follow the practices that are repugnant to the individual chancellors, while the maintenance of the complainant's right to exclude the defendants and all others would, to the extent that the patented device might otherwise be used by them to promote gambling, be a vindication of the public sentiment against gambling. It is equally obvious that, however the court may act upon complainant's asserted right to exclude, *neither the grant nor the denial of the writ of injunction would operate upon complainant's practices or habits* (which he did not acquire from the patent laws), and that the gambler, like the drunkard, is amenable to the municipal authorities alone for violations of the municipal law.<sup>50</sup>

Later Seventh Circuit rulings considering the patentable utility of gambling devices based their conclusions on findings of any legal use for the device and regularly misapplied the distinction between legality and patentable utility described in *Fuller*.<sup>51</sup> Following *Fuller*, if the

46. *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903).

47. *Id.* at 275.

48. *Id.* at 276.

49. *Id.* (stating that a measure of utility that balances an invention's good functions against its bad functions "cannot stand, because if it could, it would make the validity of the patents depend on a question of fact to which it would often be impossible to give a reliable answer").

50. *Id.* at 279 (emphasis added). The dissent, however, pointed out that gambling was illegal in all but one state and that, because the invention had gambling as its principal purpose, the patent was, in effect, condoning illegality. *Id.* at 279-81 (Grosscup, J., dissenting).

51. *Brewer v. Lichtenstein*, 278 F. 512, 513 (7th Cir. 1922) (refusing to find utility in a vending device or a punch board because "[n]o other utility than as a lottery device . . . [was] suggested in the patent . . ."); *Meyer v. Buckley Mfg. Co.*, 15 F. Supp. 640, 641 (N.D. Ill. 1936) (distinguishing *Fuller* and refusing to uphold a patent directed to a vending machine that gave the user the

device was said to have legal uses aside from its usefulness for gambling, then the court would find utility in the invention.<sup>52</sup> However, where the invention's claims were ambiguous, or where they presented utility only as a gambling device, the court refused to infer legitimate use, even where such use was demonstrated before the court.<sup>53</sup> Based on the uncertainty inherent in all such games, courts would conclude that gambling was the only possible use for the inventions and, thereby, invalidate the patents.<sup>54</sup> By the 1940s, however, courts found patentable utility in games used for innocent amusement that had no gambling purpose.<sup>55</sup>

## 2. Moral Utility and Patentable Utility Under the 1952 Patent Act

The first major revision to the original 1790 Patent Act did not come until 1952 and restated many of the fundamental principles established under the earlier law.<sup>56</sup> The Act solidified the requirements of proper subject matter, utility, novelty, and nonobviousness for patent protection.<sup>57</sup> Specifically, § 101 of the 1952 law stated that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”<sup>58</sup> However, like the earlier law, the 1952 Act did not elaborate on how the USPTO and the courts

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chance to excavate a prize from a small gravel pit with a mechanical shovel because it was “at most a device for playing a game of chance” and no other use than for gambling could be found).

52. See *supra* note 51 and accompanying text.

53. *Meyer*, 15 F. Supp. at 641. The Court stated that the coin-operated crane machine offered no utility because as “the demonstration in court showed, the invention cannot be made to so operate as to be a real vending machine delivering to the customer with certainty the merchandise he may desire. I do not believe the progress of science or the useful arts will be aided by this invention.”

54. *Id.*

55. Compare *Callison v. Dean*, 70 F.2d 55 (10th Cir. 1934) (holding a pinball machine patent invalid while it considered Justice Story's formulation of the moral utility doctrine and Robinson's “public benefit” formulation), with *Cusano v. Kotler*, 159 F.2d 159, 162 (3d Cir. 1947) (upholding a patent for a game similar to shuffleboard, stating that “[b]ecause of the cultural and prophylactic importance of games in our social structure, and the additional relevant factor of the huge annual expenditure for recreation, we can properly conclude that the creation of a new game conforms to the patent requirement of being useful”).

56. *MERGES & DUFFY*, *supra* note 7, at 8-10 (stating that although the 1836 revision of the Patent Act ended the *pro forma* registration system under the 1790 Act and instituted a formal system of examination, it was not until the 1952 Act that Congress entirely redrafted the laws governing the patent system).

57. See generally 35 U.S.C. §§ 101 (defining patentable subject matter and the requirement for utility), 102 (defining novelty as a condition for patentability), 103 (requiring non-obviousness), 112 (defining the written description requirement for patent applications as “the best mode contemplated by the inventor of carrying out his invention”) (1952).

58. 35 U.S.C. § 101.

were to apply the utility requirement.<sup>59</sup> Therefore, the courts were again left to define patentable utility without any detailed guidance from Congress.

The first comprehensive look at utility under the 1952 Patent Act came a little over a decade after it became law. In 1966, the United States Supreme Court formulated what remains the highest authority on the scope and purpose of patentable utility.<sup>60</sup> The patent at issue in *Brenner v. Manson* claimed a chemical compound that was closely related to another compound with known and useful properties.<sup>61</sup> The inventor asserted that because this closely-related compound was known to be useful, his discovery was as well.<sup>62</sup> In denying the patent for lack of utility, the Court emphasized that “[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”<sup>63</sup> Utility, therefore, is not merely a statutory requirement, but a constitutional one.<sup>64</sup>

The Court reasoned that the unpredictability of the chemical arts meant that any possible utility flowing from this discovery would have to be completely prospective.<sup>65</sup> Its close relation to a useful compound could not remedy the invention’s lack of utility.<sup>66</sup> Furthermore, the Court stated that “[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”<sup>67</sup> To be patentable, an invention must have “specific” and “substantial utility” which, by the patent grant, bestows a “specific benefit” on the public.<sup>68</sup> The Court did not express whether patentable utility excluded the concept of moral utility, instead focusing its

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59. *Id.* (merely describing that a useful invention may be eligible for protection, but offering no definition of that term).

60. *Brenner v. Manson*, 383 U.S. 519, 519 (1966). Although the Court addressed § 101 of the Patent Act in *Chakrabarty*, it dealt entirely with the issue of patentable subject matter, whereas *Brenner* specifically addressed utility under the 1952 law. *Id.* at 534.

61. *Id.* at 531 (stating that the invention’s utility was by reference to findings published in a scientific article and was purported to “reveal that an adjacent homologue of the steroid yielded by his process has been demonstrated to have tumor-inhibiting effects in mice, and that this discloses the requisite utility”).

62. *Id.*

63. *Id.* at 534.

64. Edward C. Walterscheid, “*Within the Limits of the Constitutional Grant*”: *Constitutional Limitations on the Patent Power*, 9 J. INTELL. PROP. L. 291, 327 (2002). The article discussed the general holding of *Brenner* and noted that “the Court indicated that utility is a constitutional requirement and not merely a statutory one. In so indicating, however, it failed to suggest what language of the Patent Clause created such a requirement.” *Id.*

65. *Brenner*, 383 U.S. at 532.

66. *Id.* at 536.

67. *Id.*

68. *Id.* at 534-35. The Court explained:

definition on the contractual quality of the public benefit derived from the patent grant.<sup>69</sup>

It was not until 1977 that a court specifically addressed the concept of moral utility under the 1952 Patent Act; the patent at issue was for a device used solely for gambling.<sup>70</sup> In *Ex parte Murphy*,<sup>71</sup> the Patent and Trade Office Board of Appeals reversed the examiner's rejection of a slot machine patent on the basis of 35 U.S.C § 101.<sup>72</sup> The court based its finding on the simple language of the 1952 law and held that there was no basis in the statute to conclude that gambling machines were completely void of patentable utility.<sup>73</sup> Furthermore, the court emphatically denied any ability of the USPTO to judge morality in patent prosecutions for gambling devices and stated:

[W]e think this Office should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent on a game of chance if the requirements of the Patent Act otherwise have been met.<sup>74</sup>

Therefore, the USPTO will not reject patents for gambling devices for lack of utility based on moral reservations.

The predecessor to the modern United States Court of Appeals for the Federal Circuit stated a similar view regarding the USPTO's role in determining public safety and the patenting of pharmaceutical compounds. In *re Anthony*<sup>75</sup> in 1969 and *In re Watson*<sup>76</sup> in 1975 both concerned appeals from USPTO rejections based on lack of utility and

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[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation . . . . The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification in permitting an applicant to engross what might prove to be a broad field.

*Id.*

69. *Id.* (stating that a patent with only vague utility “may confer power to block off whole areas of scientific development, without compensating benefit to the public”).

70. *Ex parte Murphy*, 200 U.S.P.Q. (BNA) 801, 803 (Pat. & Trademark Off. Bd. App. 1977).

71. *Id.*

72. *Id.*

73. *Id.* at 802 (referring to 35 U.S.C. § 101 (1952), which states simply that “[w]hoever invents or discovers a new and useful process . . . or any new and useful improvement thereof may obtain a patent”).

74. *Id.* at 803.

75. *In re Anthony*, 414 F.2d 1383 (C.C.P.A. 1969).

76. *In re Watson*, 517 F.2d 465 (C.C.P.A. 1975).

rejected the non-“injurious” component of Justice Story’s utility formulation.<sup>77</sup> In both cases, the examiner rejected the applicants’ inventions for lack of utility because the pharmaceutical compounds, when applied to humans, had serious potential for harm or possible deadly side effects.<sup>78</sup> The United States Court of Customs and Patent Appeals reversed the rejections, stating that safety was not a component of patentable utility.<sup>79</sup>

Furthermore, in rejecting the administration of public safety for the USPTO due to the explicit reservation of that role to agencies such as the Food and Drug Administration, the court explicitly stated that:

[w]ith regard to the . . . nature of “safety” in the field of drugs . . . we take judicial notice that many valued therapeutic substances, . . . when administered to lower animals or humans, entail certain risks or may have undesirable side effects. True it is that such substances would be more useful if they were not dangerous . . . but the fact remains that they are useful, useful to doctors, veterinarians and research workers, useful to patients . . . and so are useful within the meaning of 35 U.S.C. § 101.<sup>80</sup>

In 1980, the Supreme Court again took up the proper interpretation of 35 U.S.C. § 101, but focused on the definition of patentable subject matter instead of utility.<sup>81</sup> In *Diamond v. Chakrabarty*,<sup>82</sup> the patent at issue claimed a “human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil.”<sup>83</sup> Spe-

77. See *supra* notes 14, 45 and accompanying text (explaining Justice Story’s moral utility definition and a later application resulting in the “injurious” prong of his test for patentable utility).

78. *Anthony*, 414 F.2d at 1386-93. The USPTO granted a patent for the active ingredient in the drug Monase after the Upjohn Company proffered evidence of clinical safety and relatively low incidence of side effects in both its patent application and for Food and Drug Administration (FDA) approval. *Id.* After prolonged market use, however, Upjohn requested that the FDA remove the drug from availability due to several publicized incidents of acute blood disease and death. *Id.* As a result of the FDA’s removal of the drug from use, the USPTO revoked the patent for lack of utility citing those safety concerns. *Id.* See also *Watson*, 517 F.2d at 474-75 (rejecting a patent application for lack of utility on an over-the-counter mouthwash containing 0.2% hexachlorophene after the FDA issued a directive indicating that the compound had significant toxic effects in humans and specifically limited the acceptable use of the compound to no more than 0.1%).

79. *Anthony*, 414 F.2d at 1394; *Watson*, 517 F.2d at 475.

80. *Watson*, 517 F.2d at 475. The case referred to *In re Hartop*, 311 F.2d 249, (C.C.P.A. 1962), which refused to reserve safety as a function of the USPTO, stating:

We believe that Congress has recognized this problem and has clearly expressed its intent to give statutory authority and responsibility in this area to Federal agencies different than that given to the Patent Office. This is so because the standards established by statute for the advertisement, use, sale or distribution of drugs are quite different than the requirements under the Patent Act for the issuance of a patent.

*Id.*

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

82. *Id.*

83. *Id.* The Court explained that:

cifically, the patent claimed not only the process to produce the bacterium, but also the bacterium itself.<sup>84</sup> The issue before the Court was whether 35 U.S.C. § 101's restriction of patents to only a "process, machine, manufacture, or composition of matter" could include the claimed bacterium.<sup>85</sup> In opposition to issuing a patent for the bacterium, the USPTO argued first that the language of § 101 did not include microorganisms<sup>86</sup> and, more importantly, that until Congress expressly authorizes patent protection for living organisms, the office should not so greatly expand patentable subject matter.<sup>87</sup> The USPTO argued specifically that "genetic technology was unforeseen when Congress enacted § 101 . . . [and] . . . [t]he legislative process . . . is best equipped to weigh the competing economic, social, and scientific considerations involved . . ."<sup>88</sup>

Following the evolution of the Patent Act, and in light of Committee Reports accompanying the 1952 Act, the Court relied heavily on the fact that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'" and reversed the

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Chakrabarty and an associate discovered that plasmids control the oil degradation abilities of certain bacteria. In particular, the two researchers discovered plasmids capable of degrading . . . two components of crude oil. In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil.

*Id.*

84. *Id.* at 305-06 (describing the patent claims as being "of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves").

85. *Id.* at 307.

86. *Chakrabarty*, 447 U.S. at 310-11. The Court related the USPTO's first argument that relied

on the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection. In the [USPTO's] view, the passage of these Acts evidences congressional understanding that the terms 'manufacture' or 'composition of matter' [from 35 U.S.C. § 101] do not include living things; if they did, . . . neither Act would have been necessary.

*Id.* at 310-11.

87. *Id.* at 314.

88. *Id.* at 314-15. The USPTO relied on the earlier decision of *Parker v. Flook*, 437 U.S. 584, 596 (1978), which held that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress," and stated that "*Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*." *Id.*

USPTO's rejection.<sup>89</sup> The Court concluded that Chakrabarty's bacterium itself was patentable because it was a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity . . ."<sup>90</sup> Furthermore, the Court noted that the provisions of § 101, coupled with its legislative history,

have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.<sup>91</sup>

Notably, the Court did not conclude its opinion merely by illuminating the legal reasoning behind its decision to grant patent protection in living organisms.<sup>92</sup> The USPTO implored the Court to consider the scientific and social implications of allowing patents on life.<sup>93</sup> Specifically, the USPTO asked the Court to consider testimony from notable scientists about the dangers of genetic engineering and the slippery slope of proceeding without clear congressional guidance that "may result in a loss of genetic diversity, and . . . may tend to depreciate the value of human life."<sup>94</sup> Sweeping aside this argument against patenting the products of genetic manipulation, the Court stated:

[t]he grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether [Chakrabarty's] claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.<sup>95</sup>

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89. *Id.* at 309. The Court noted that "[t]his same language was employed by P. J. Federico, a principal draftsman of the 1952 recodification, in his testimony regarding that legislation: '[Under] section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man . . .'" (citations omitted).

90. *Chakrabarty*, 447 U.S. at 309-10 ("Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character [and] use.").

91. *Id.* at 315 (referring to Jefferson's broad goals for the patent system under the 1790 Act). See *supra* note 27 and accompanying text.

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

93. See *id.* See also *supra* note 1 and accompanying text.

94. *Id.*

95. *Id.* at 317. Canute the Great, who lived in the eleventh century A.D., is regarded as the first ruler of a united England. Legend has it that Canute had learned that his flattering courtiers claimed he was so powerful, he could command the tides of the sea to go back. Canute, understanding his limitations better than his courtiers (as well as the height of the tides on that

Furthermore, the Court noted that Congress had, in fact, limited the subject matter of patents under 42 U.S.C. § 2181(a) by specifically excluding inventions utilizing nuclear material from patentable subject matter.<sup>96</sup> However, Congress alone should make any decision to exclude the products of genetic manipulation from patentable subject matter.<sup>97</sup>

Traditionally, Justice Story's formulation of moral utility also prohibited patents for illegal devices that were "injurious to the . . . good policy . . . of society."<sup>98</sup> However, it is unclear what effect outright illegality or banning of an invention by Congress or federal agencies might have on a court's evaluation of patentable utility.<sup>99</sup> In *Whistler Corp. v. Autotronics Inc.*,<sup>100</sup> the United States District Court for the Northern District of Texas alluded to the effect of a complete ban and rejected the argument that a patent for a radar detection device used in automobiles was invalid for lack of utility because its primary purpose was to circumvent law enforcement. The court concluded that the legislative branch was more capable of determining the ability of the public to use the devices and stated that "[u]nless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar patentees are entitled to the protection of the

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particular day) had his throne carried to the seashore and sat on it as the tide came in, commanding the waves to advance no further. See generally Barrie Markham Rhodes, *Canute (Knud) The Great*, The Viking Network, at <http://www.viking.no/e/people/e-knud.htm> (last visited Nov. 2, 2003).

96. *Chakrabarty*, 447 U.S. at 318. 42 U.S.C. § 2181(a) directs that "[n]o patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is hereby revoked, and just compensation shall be made therefor." 42 U.S.C. § 2181 (2001).

97. *Chakrabarty*, 447 U.S. at 318. The Court noted that:

Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering . . . [o]r it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.

*Id.*

98. See *supra* note 34 and accompanying text.

99. Congress has, however, specifically prohibited the USPTO from granting patents directed to atomic weapons by removing them from patentable subject matter. See generally 42 U.S.C. § 2181(a); *supra* note 96 and accompanying text.

100. *Whistler Corp. v. Autotronics Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988) (noting that "[n]otwithstanding Whistler's evidence to the contrary that the instant detectors have other uses, the court remains of the view that the primary and almost exclusive purpose for the radar detectors . . . is to circumvent law enforcement attempts to detect and apprehend those who violate the law").



patent laws."<sup>101</sup> This ruling suggested that a congressional declaration of illegality of an invention might lead to patent invalidity due to lack of utility. Although this ruling only represents the conclusion of one federal court, and the USPTO and higher federal courts have not yet addressed this specific issue, the decision implied that the legal reasoning connecting illegality with patentable utility was at least attainable.

### 3. *The Modern State of Utility*

Since the Supreme Court rulings of *Brenner* and *Chakrabarty* determined the meaning of § 101, the courts, scholars, and the USPTO have struggled to formulate a workable definition of patentable utility.<sup>102</sup> Most modern explanations include *Brenner's* requirements of specific and substantial utility.<sup>103</sup> Although the USPTO does not include specific references to Justice Story's moral component in their examination process for all applications, the agency does consider the doctrine in some instances.<sup>104</sup> However, the USPTO does not specifically recognize the "benefit derived by the public" component of utility evident in the Supreme Court's reasoning in *Brenner*.<sup>105</sup> In 1999, the Federal Circuit Court of Appeals considered the requirements for

101. *Id.* The court went further to conclude that "the matter is one for the legislatures of the states, or for Congress to decide . . ." and that, "[a]bsent clear and convincing evidence to the contrary, this court cannot and should not substitute its own views in place of those of the PTO, the several legislatures, or the Congress." *Id.*

102. See cases cited *supra* note 36; *Geneva Pharms., Inc. v. Glaxosmithkline*, 213 F. Supp. 2d 597, 610 (E.D. Vir. 2002) (using a pre-1952 formulation of patentable utility that included morality: "[a] patent possesses utility 'if it will operate to perform the functions and secure the results intended, and its use is not contrary to law, moral principles, or public policy'" (quoting *Callison v. Dean*, 70 F.2d 55, 58 (10th Cir. 1934)).

103. *Philips Petroleum Co. v. U.S. Steel Corp.*, 6 U.S.P.Q.2d (BNA) 1065, 1105 (D. Del. 1987), *aff'd*, 865 F.2d 1247 (Fed. Cir. 1989) (finding utility in a chemical product where because "the description of utility . . . is specific enough so as not to be insufficient as a matter of law."); Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). The Guidelines state: "A claimed invention must have a specific and substantial utility. This requirement excludes 'throw-away,' 'insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. § 101." *Id.*

104. See *infra* notes 153-158 and accompanying text.

105. Compare *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (stating that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public . . .") with Utility Examination Guidelines, 66 Fed. Reg. at 1095. The Guidelines state:

By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established utility, the examiner will reject the claim under section 101.

66 Fed. Reg. at 1095.

patentable utility in *Juicy Whip, Inc. v. Orange Bang, Inc.*<sup>106</sup> Though the court limited the concept of moral utility as applied to mechanical inventions, the court nevertheless signaled that it might consider morality a factor of utility under different conditions.<sup>107</sup>

a. *Juicy Whip v. Orange Bang*: The Federal Circuit's Consideration of Moral Utility

The invention in *Juicy Whip* concerned a simple device found in convenience store beverage dispensers that eliminated the step of mixing the beverage in the machine before dispensing.<sup>108</sup> *Juicy Whip*'s patent was entitled "Post-Mix Beverage Dispenser With an Associated Simulated Display of Beverage."<sup>109</sup> The post-mix dispenser stored beverage concentrate and water in different locations and did not mix the two until the customer dispensed the drink.<sup>110</sup> A pre-mix dispenser, however, stored the combined concentrate and water in a top-mounted display bowl.<sup>111</sup> The lower court concluded that the purpose of the display bowl was solely to stimulate impulse buying.<sup>112</sup> *Juicy Whip*'s post-mix invention eliminated the problems of contamination and frequent re-filling but nevertheless included the pre-mix display bowl on its invention to increase impulse sales; *Juicy Whip* included this deception as one of its claims.<sup>113</sup>

106. *Juicy Whip v. Orange Bang*, 185 F.3d 1364, 1364 (Fed. Cir. 1999).

107. See *infra* note 123 and accompanying text.

108. *Juicy Whip*, 185 F.3d at 1365.

109. *Id.*

110. *Id.*

111. *Id.* *Juicy Whip* specifically claimed:

[A] post-mix beverage dispenser of the type having an outlet for discharging beverage components in predetermined proportions to provide a serving of dispensed beverage, the improvement which comprises: *a transparent bowl having no fluid connection with the outlet and visibly containing a quantity of fluid*; said fluid being resistant to organic growth and simulating the appearance of the dispensed beverage . . . .

*Id.* (emphasis added).

112. *Id.* at 1366. The Court stated that

[t]he [lower] court further held that the invention lacked utility because it 'improves the prior art only to the extent that it increases the salability of beverages dispensed from post-mix dispensers'; an invention lacks utility, the court stated, if it confers no benefit to the public other than the opportunity for making a product more salable.

*Juicy Whip*, 185 F.3d at 1366.

113. *Id.* at 1365-66. The Court stated that the specific claims that

said bowl positioned relative to the outlet to create the visual impression that said bowl is the reservoir and principal source of the dispensed beverage from the outlet; and said bowl and said quantity of fluid visible within said bowl cooperating to create the visual impression that multiple servings of the dispensed beverage are stored within said bowl.

*Id.*

Orange Bang moved for summary judgment on Juicy Whip's infringement action on the ground that the invention lacked utility, and the district court granted the motion.<sup>114</sup> The district court reasoned that the deceptive purpose of the invention was enough to invalidate the patent for lack of utility and that the claimed improvement over pre-mix dispensers was "not independent of its deceptive purpose, and . . . [was] . . . insufficient to raise a disputed factual issue . . . to a jury."<sup>115</sup> To support its view, the district court relied on the reasoning of Justice Story in *Lowell v. Lewis* and two pre-1952 Patent Act decisions.<sup>116</sup>

The Federal Circuit Court of Appeals reversed the decision and re-evaluated the concept of moral utility.<sup>117</sup> The court noted that "the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years" but did not specifically discard the reasoning.<sup>118</sup> Merely, the court declined to follow the reasoning offered in the early twentieth century cases and stated that "the fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility."<sup>119</sup> Significantly, the court noted that by Supreme Court reasoning, "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."<sup>120</sup> In conclusion, the court emphasized that:

Congress is free to declare particular types of inventions unpatentable for a variety of reasons . . . [but] until such time as Congress does so, . . . we find no basis in § 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.<sup>121</sup>

Like the Supreme Court in *Diamond v. Chakrabarty*, the court also noted 42 U.S.C § 2181(a) and the congressional exclusion of inventions utilizing nuclear material.<sup>122</sup> Therefore, the Federal Circuit Court of Appeals only limited the application of moral utility to certain types of mechanical inventions and cited Congress as the true ar-

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114. *Id.* at 1366.

115. *Id.*

116. *Id.* at 1366-67.

117. *Id.* at 1365.

118. *Juicy Whip*, 185 F.3d at 1366-67.

119. *Id.* at 1367 (noting the "significant" advancement of the sciences offered by such inventions as cubic zirconium, imitation leather, and simulated grill markings on hamburger patties).

120. *Id.* at 1368 (quoting *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880)).

121. *Id.*

122. *Id.*

biter of morality as applied to inventions.<sup>123</sup> Arguably, this limitation might allow the court to re-examine the doctrine in different contexts should the need arise.

#### b. Scholarly Recognition of Moral Utility

Professor Donald S. Chisum recognized the Supreme Court requirement enunciated in *Brenner* and included the moral component kept alive by the *Juicy Whip* decision as one of the tests for patentable utility.<sup>124</sup> Chisum recognized three basic tests for patentable utility: “First, it must be operable and capable of use. It must operate and perform the functions and secure the result intended. Second, it must operate to achieve some minimum human purpose. Third, it must achieve a human purpose that is not illegal, immoral or contrary to public policy.”<sup>125</sup> To further explain the third requirement, he stated that “an invention must perform some function of positive benefit to society.”<sup>126</sup>

However, like the Federal Circuit in *Juicy Whip*, Chisum’s recognition of a beneficial or moral component to patentable utility came with sharp limitations. The “public policy doctrine” should only destroy an invention’s patentable utility “if the invention cannot be used for any honest and moral purpose.”<sup>127</sup> Furthermore, due to the ever-shifting and expanding concept of morality within our society, “the courts should not apply subjective ideas of honesty and morality” when considering utility.<sup>128</sup> Apart from the statements in *Juicy Whip* and the narrow deliberation of the topic by Professor Chisum, negligible authority exists for modern application of morality to patentable utility.<sup>129</sup>

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123. *Id.*

124. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 4.03 Utility: Illegal, Immoral, and Harmful Inventions (2002).

125. 1 *id.* § 4.01 Utility: Introduction, at 4-2.1.

126. 1 *id.* at 4-2 (referring to The Patent Act of 1790 which “extended patents to any *useful* art” and the 1793 and 1836 laws that continued the same requirement; further, that “[a] person cannot obtain a valid patent for an invention that will not in fact operate to perform its designated function or that will only perform mischievous or harmful functions”).

127. 1 *id.* § 4.03, at 4-17.

128. 1 *id.*

129. Reflecting what might be considered scholarly rejection of the moral utility concept, Professor Chisum relied entirely on two sources in support of his ideas about morality and patentable utility: one law school casebook author’s point of view (R. CHOAT, PATENT LAW – CASES AND MATERIALS 380 (1973)), and broad dicta from *Ex parte* Murphy, 200 U.S.P.Q. (BNA) 801, 802 (Pat. & Trademark Off. Bd. App. 1977). In *Ex parte* Murphy, the court stated that:

We find ourselves in agreement with appellants and recognize that while some may consider gambling to be injurious to the public morals and the good order of society, we cannot find any basis in 35 U.S.C. § 101 or related sections which justify a conclusion

### c. The USPTO and Moral Utility

The USPTO revised its Utility Examination Guidelines in 1995 and 2001 to more closely reflect the utility formulation announced in *Brenner*. In doing so, the USPTO focused its definition on specific, substantial, and credible utility.<sup>130</sup> The 2001 revised guidelines stated:

[i]f the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e. it has a 'specific and substantial utility') and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.<sup>131</sup>

Neither the guidelines nor the training materials accompanying them made any reference to a moral requirement for patentable utility.<sup>132</sup> Although the guidelines did not alter the substantive requirements of the Patent Act, nor did they constitute "rulemaking carrying the force of law," they provided insight into the examination process and the basis for the USPTO procedure for evaluating patentable utility.<sup>133</sup>

Before officially adopting the guidelines in 2001, the USPTO opened them for public debate.<sup>134</sup> Comments on the new utility examination guidelines raised some pertinent issues regarding morality as a function of patentable utility.<sup>135</sup> In particular, individual comments focused on the patentability of human genetic sequences and the confusion about the possibility of patents conferring ownership

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that inventions which are useful only for gambling ipso facto are void of patentable utility.

*Id.*

130. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). See also *Revised Interim Utility Guidelines Training Materials* 3 (stating that "[t]he examiner should determine whether any asserted utility is specific and substantial, and if so, determine whether such asserted utility is credible"), available at <http://www.uspto.gov/web/menu/utility.pdf> (last visited Nov. 3, 2003).

131. Utility Examination Guidelines, 66 Fed. Reg. at 1098.

132. *Id.* at 1092.

133. *Id.* at 1098. "The Guidelines do not alter the substantive requirements of 35 U.S.C. § 101 . . . . The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable.")

134. Revised Interim Utility Examination Guidelines; Request for Comments; Correction, 65 Fed. Reg. 3425 (Jan. 21, 2000).

135. See generally PATENT & TRADEMARK OFFICE, PUBLIC COMMENTS ON THE UNITED STATES PATENT AND TRADEMARK OFFICE, "REVISED UTILITY EXAMINATION GUIDELINES," available at <http://www.uspto.gov/web/offices/com/sol/comments/utlguide/index.html> (last visited Nov. 3, 2003). Most individual comments concerned the issue of patents on the human genome claiming certain property rights in humans; the USPTO flatly rejected these comments. However, scientific research organizations reacted favorably to the new guidelines.

rights in humans.<sup>136</sup> These comments implicated the moral utility doctrine as grounds for rejecting patents related to discoveries surrounding the human genome project and human gene sequences in general.<sup>137</sup> The USPTO flatly rejected these comments and stated broadly that “[p]atents do not confer ownership . . .” but merely the right to exclude, which is a limited property right that does not include title to the product of the invention claimed by the patent.<sup>138</sup> The office went further to emphasize that patentable utility makes no consideration of an invention’s marketability and that the sole determination of utility is confined to those inventions exhibiting a “specific, substantial, and credible utility.”<sup>139</sup>

### B. *The Modern Challenge to Moral Utility*

Even as judges, scholars, and the USPTO minimize the importance of moral utility, emerging technologies have renewed interest in the doctrine and point to its continued viability. As the USPTO and Congress grapple with inventions that might transform traditional notions of humanity and medical science through genetic manipulation, the doctrine of moral utility has emerged as an expedient, albeit imperfect, solution. The USPTO’s reaction to recent applications directed to inventions that involved mixing human and nonhuman DNA and the current debate surrounding human cloning provide the clearest

136. *Id.*

137. *Id.* See *id.* cmt. 14 (Jim Huber, Director of Molecular and Human Genetics, Baylor College of Medicine, stated “I believe that at least [sic] human genomic sequence goes to the core of what it means to be human and no individual or corporation should have control or ownership of something so basic.”). Debra Harry, Director, Indigenous Peoples Council on Biocolonialism, stated:

The prudent course would be for the Patent and Trademark Office to seek clarification from Congress on whether naturally occurring genetic sequences are properly subject to the patenting system. In the interim, the USPTO should impose a moratorium on patenting of genetic sequences. The extension of patents to genetic sequences is a profound misuse of patent system and represents the privatization, only to support corporate interests, of something that is not an invention and should not be subject to corporate ownership. No individual, institution, or corporation should be able to claim ownership over species or varieties of organisms.

*Id.* cmt. 39.

138. Utility Examination Guidelines, 66 Fed. Reg. 1093 (Jan. 5, 2001). The USPTO’s view regarding the scope of rights conferred by the patent comports with most interpretations. See MERGES & DUFFY, *supra* note 7, at 48. The authors stated that the patent,

[u]nlike other forms of property, . . . includes *only* the right to exclude *and nothing else*. Patent rights are wholly *negative* rights—rights to stop others from using—not positive rights to use the invention. Thus, inventors and patent holders may be barred from practicing their inventions without creating any conflict with the basic patent.

*Id.* (emphasis in original).

139. Utility Examination Guidelines, 66 Fed. Reg. at 1094.

evidence to date of moral utility's persistent presence in modern patent law. Furthermore, inadequate congressional responses to mounting public pressure against human cloning signal another possibility for application of the doctrine.

### 1. *Chimeras and the Human Cloning Debate*

The USPTO faced a particularly controversial situation in 1998 when an inventor forced the agency to deal with new questions about moral utility. Biotechnology activist Jeremy Rifkin and cell biologist Stuart Newman filed an application involving chimeric embryos that contained both human and nonhuman cells.<sup>140</sup> A chimera is "an imaginary monster compounded of incongruous parts" or as the application related, "an individual, organ, or part consisting of tissues of diverse genetic constitution . . ." <sup>141</sup> The Rifkin-Newman application included variations of human chimeras including one claim for a part human, part rat creation.<sup>142</sup> The application was highly publicized by the scientists as an attempt to prevent others from practicing what they considered an immoral invention and to spark debate concerning the limits of morality and science in patent law.<sup>143</sup>

The USPTO responded with an immediate press release in an attempt to stem the tide of criticism directed toward the office and its policies. The release recognized that the USPTO must issue patents "without discriminating against a particular field of technology" and stated that "[i]t is the position of the USPTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."<sup>144</sup>

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140. See Ho, *supra* note 3, at 247.

141. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 223 (1989).

142. See Slater, *supra* note 3, at 21. "Concoctions included the huMouse, a mixture of man and mouse; the humanzee, a cross between a human and a chimpanzee; and blends of human with pig and human with baboon . . . . The [inventions] could potentially be used to study embryonic development, raise organs for transplants, or test new drugs." It is important to note that the chimeras claimed in the application are not hybrids, or the heterogeneous genetic blending of two animals where every cell of the resulting animal would contain a portion of each host's DNA. By Rifkin's invention, the resulting animal would be made up of tissue containing the complete genetic material of each host, creating a disconnected patchwork of human and non-human cells.

143. See Ho, *supra* note 3, at 247-48.

144. U.S. PATENT & TRADEMARK OFFICE, FACTS ON PATENTING LIFE FORMS HAVING A RELATIONSHIP TO HUMANS (Apr. 1, 1998), available at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (last visited Nov. 3, 2003).

The USPTO later retracted its stance on moral utility and instead rejected the application on subject matter grounds.<sup>145</sup> The examiner's explanation of the rejection relied on earlier USPTO guidance concerning the patentability of animals which stated that "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."<sup>146</sup> Although the USPTO did not specify which constitutional provision gave rise to this limitation, most scholars believe that the office was referring to the Thirteenth Amendment prohibition on slavery.<sup>147</sup> Since the initial rejection in 1999, the USPTO has made no further statements in reaction to the Rifkin-Newman application.<sup>148</sup>

Recent statements by the USPTO in response to press inquiries about an issued patent further explain the stance taken in response to the 1998 Chimera application. In April 2001, the USPTO granted the University of Missouri a patent that may include human cloning.<sup>149</sup> Generally, the patent covered a process for genetically modifying pigs for use as human organ donors.<sup>150</sup> The specific patent claims described a process for turning unfertilized eggs into embryos, the production of cloned mammals using that technique, and specifically claimed the use of human eggs.<sup>151</sup> As stated earlier, based on the human-animal chimera rejection, the USPTO policy against patenting humans rested on the Constitution's prohibition of slavery. However, in light of recent controversy surrounding the University of Missouri patent, the USPTO stated that "the agency was not using the 13th [sic] Amendment argument anymore, but was not granting patents on humans because it had not received any guidance from Congress or

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145. See Ho, *supra* note 3, at 249-50 (citing *Patent Application is Disallowed as 'Embracing' a Human Being*, 58 PAT., TRADEMARK & COPYRIGHT J. 203 (1999)). It should be noted that, as a matter of policy, the USPTO will not release any official comments about an examiner's reasoning for rejection of a specific application; all information about the rejected application comes from the applicants, Rifkin and Stewart.

146. *Id.* at 250 (citing U.S. Patent & Trademark Office, *Animals – Patentability*, 1077 OFF. GAZ. PAT. OFFICE 24 (1987)).

147. *Id.* at 251.

148. See Slater, *supra* note 3, at 20-28 (noting that the Rifkin application was still being evaluated by the USPTO and was rejected by the office for the third time in August 2000). The applicants have refused to submit detailed information concerning the application or the USPTO's grounds for rejection as such information "could jeopardize their ability to secure a patent on their process." *Id.*

149. Andrew Pollack, *Debate on Human Cloning Turns to Patents*, N.Y. TIMES, May 17, 2002, at 14.

150. See generally U.S. Patent No. 6,211,429 (issued Apr. 3, 2001), available at <http://patft.uspto.gov/netahtml/srchnum.htm> (last visited Oct. 20, 2003).

151. *Id.* at claims 1, 20, and 12, respectively.



the courts saying it should do so.”<sup>152</sup> Although the exact limits of the University of Missouri patent may not be clearly drawn to humans, several authorities speculated that the patent could give the holder the exclusive right to this process as applied to humans and its products.<sup>153</sup>

Recent testimony by a USPTO representative before the Presidential Council on Bioethics provided the clearest enunciation to date of the Office’s policy toward human cloning and moral utility. A Supervisory Patent Examiner advised the Council on behalf of the USPTO to recommend that Congress clarify the current patentable subject matter statutes rather than rely on the moral utility doctrine to effect any change in current United States patent laws.<sup>154</sup> Referring to the prior USPTO statements surrounding the Rifkin-Stewart chimera application, and congressional testimony regarding the patentability of humans, she stated that:

[i]n the 15 years since it was notified of the USPTO’s interpretations, Congress has apparently acquiesced to the USPTO interpretation . . . [that] . . . [t]he current policy [of the USPTO] . . . is to consider any claim encompassing a human being at any stage of development . . . not to be patent eligible subject matter under 35 U.S.C. § 101.<sup>155</sup>

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152. See Pollack, *supra* note 149. Quinn, a USPTO Representative, also stated that the patent office did not comment on individual patents, but had not changed its policy of not issuing patents drawn to humans. *Id.*

153. *Id.* The article notes the opinion of several attorneys that concluded that the patent appears to specifically claim a process for cloning a human embryo. However, the specific claim is drawn to an embryo, which courts have concluded is not a person through abortion-rights precedent. This fact may limit any application of the Thirteenth Amendment to this or any other particular patent claiming embryos rather than humans. *Id.*

154. Karen Hauda, Remarks at the Meeting of the President’s Council on Bioethics, Session 5, Regulation 3: Patentability of Human Organisms 1, History and Current Law (June 20, 2002), available at <http://www.bioethics.gov/transcripts/jun02/jun21session5.html> (last visited Oct. 20, 2003) (stating that “[t]he President’s Council on Bioethics may also want to consider recommending that Congress clarify its intent regarding patent-eligible subject matter”).

155. *Id.* Hauda further stated:

It should be noted, however, that in holding the microorganisms for patent eligible subject matter, the Supreme Court [in *Diamond v. Chakrabarty*] was aware of the lower court’s view that we are not dealing with patent eligibility of all living things, including man. The USPTO concluded that inventions covering human beings are not within the scope of section 101, and in 1987, published a notice in the USPTO’s official gazette advising the public of its conclusions. The USPTO concluded that Congress never intended for a human being to be considered a manufacturer [sic] or a composition of matter under the patent law. More recently, an immediate advisory issued in 1998, the USPTO reiterated its policy that an invention, including within its scope a human being, could not be considered to be patentable subject matter under 35 U.S.C. § 101 because it would be against public policy to do so. Shortly after the USPTO published its notice of intent not to patent human beings, it informed Congress of the decision by direct testimony in a 1987 hearing before a subcommittee of the Committee on Judiciary, House of Representatives, on the patents on the Constitution of Trans-

Furthermore, she stated that the USPTO's reasoning for this policy was based on three considerations. First, § 101 itself restricts patents to the "categories of process, machine, manufacture, or composition of matter" and the ordinary meaning of these terms does not include a human being.<sup>156</sup> Second, "[c]onferring exclusive rights over a human being would also raise constitutional questions . . . ."<sup>157</sup> Third, and most importantly, "courts have interpreted the utility requirement to exclude inventions deemed to be injurious to the well-being, good public policy, or good morals of society."<sup>158</sup> In reference to the USPTO's last consideration, the Patent Examiner specifically noted that although the *Juicy Whip* decision left this last consideration uncertain, there was viable judicial reasoning concluding that patents may be invalid for lack of utility on morality grounds.<sup>159</sup> The

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genic Animals. On June 11th, 1987 the USPTO's Assistant Commissioner testified that a claim, including a human being within its scope, will not be considered to be patentable subject matter.

*Id.*

156. *Id.* See 35 U.S.C. § 101 (1952); see also *supra* text accompanying note 58.

157. See Hauda, *supra* note 154; see also Arti Rai, Remarks at the Meeting of the President's Council on Bioethics, Session 6, Regulation 4: Patentability of Human Organisms 2: Ethics and Public Policy (June 20, 2002), available at <http://www.bioethics.gov/transcripts/jun02/june21session6.html> (last visited Oct. 20, 2003). Rai also stated:

The 13th Amendment, as many of you probably know, bans not only slavery, but also what is known as involuntary servitude. And it seems to me that a patent on a human people could be deemed to impose an involuntary servitude. Now, the 13th Amendment jurisprudence . . . has needless to say focused on cases where there has been a physical or legal compulsion to work . . . . But it seems to me that property rights that entirely disallow an individual from choosing his or her employment, or choosing to work in the first place, could fall within the scope of the amendment. In addition, the patentee's control [of an invention directed to human cloning and] of the patented beings' right to reproduce . . . seems to . . . implicate the protections of the 14th Amendment . . . . So the 13th and 14th Amendments provides [sic] the best justification for the PTO's current policy to the extent that it disallows product patents on full human beings.

*Id.*

158. See Hauda, *supra* note 154.

159. *Id.* Hauda stated:

Any actions taken by the USPTO must have legal basis under Title 35 of the United States Code, as interpreted by the Federal Courts of the United States. The USPTO also lacks substantive rule making authority. Legal challenges will therefore likely be raised to the USPTO's interpretation of statutory subject matter under Section 101. A challenge to the non-patentability of human beings would be a case of first impression to the court. The resulting outcome, especially on public policy grounds, is uncertain. In the *Juicy Whip* case, the Federal Circuit questioned the continued viability of the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes, noting that this reasoning has not been applied broadly in recent years. In addition to the role of the USPTO as a gatekeeper for the public, it is recognized that strong patent protection has been vital to the development and commercialization of innovations in biotechnology.

*Id.*

USPTO's official position, therefore, is that moral utility is still a viable basis for an application's rejection, but that in light of *Juicy Whip*, that basis is tenuous. Additionally, the USPTO contends that congressional clarification on patentable subject matter, rather than reliance on their own formulation of the utility requirement, would be the best avenue for regulation of patents directed to human cloning.<sup>160</sup>

## 2. Congressional Responses to Human Cloning

In late July 2001, the United States House of Representatives passed the Human Cloning Prohibition Act of 2001 (H.R. 2505), by a majority of over one hundred votes.<sup>161</sup> The bill provided criminal and civil penalties for anyone who knowingly performs human cloning, participates in an attempt to clone a human, or receives any product of human cloning.<sup>162</sup> The bill, however, contained no restrictions on patents directed to human cloning.<sup>163</sup> Since 2001, congressional efforts to push through an anticloning measure have not resulted in a federal law. Four anticloning measures were active during the 107th Congress.<sup>164</sup> One Senate bill, S. 1899, was identical to H.R. 2505, and had more support than similar Senate bills, with the names of no less than thirty senators attached to it as cosponsors.<sup>165</sup> However, Senate

160. See Hauda, *supra* note 154. Hauda also stated:

The President's Council on Bioethics may also want to consider recommending that Congress clarify its intent regarding patent-eligible subject matter . . . . However, any restrictions that would limit the patent eligibility of biotechnology inventions must be carefully crafted to avoid unintended consequences, such as general negative effect on the investment in the biotechnology sector.

*Id.*

161. See generally Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. § 302 (2002).

162. H.R. 2505. The Act states:

It shall be unlawful for any person, entity, public or private, in or affecting interstate commerce, knowingly to perform or attempt to perform human cloning; to participate in an attempt to perform human cloning; to ship or receive for any purpose an embryo produced by human cloning or any product derived from such an embryo.

The measure provides for imprisonment for up to ten years and a civil fine of "not less than \$1,000,000 . . . ."

*Id.*

163. See Pollack, *supra* note 149 (quoting the leading proponent of the human cloning ban in the Senate, Sam Brownback, as stating "I think the patent office will appreciate having [the] clarity [of a federal human cloning ban], given the applications that are coming into the patent office"). It is unclear, however, as to what clarity the Senator referred, since no bill yet introduced has considered patent issues as part of the cloning ban.

164. S. 1899, 107th Cong. (2002); S. 2439, 107th Cong. (2002); and S. 1893, 107th Cong. (2002) were all bipartisan measures while S. 1758, 107th Cong. (2001) was sponsored solely by Democrats.

165. The Human Cloning Prohibition Act of 2001 passed the House of Representatives as H.R. 2505, 107th Cong. (2001); the identical Senate bill was S. 1899. The other active Senate

activity buried S. 1899 in committee in two sets of hearings and the focus of all information-gathering was entirely on the implications of the ban on stem cell research; no debate surfaced on the prohibition's effects on the patent system or consideration of the USPTO's request for clarification on the subject.<sup>166</sup>

Changes in the political composition of Congress resulting from the November 2002 elections renewed the likelihood that an anticloning measure will be passed during the 108th Congress.<sup>167</sup> Immediately after the elections, the White House announced that several measures that had been stalled during the 107th Congress, including a ban on reproductive human cloning, would be top priorities on the President's agenda.<sup>168</sup> Also, the 108th Congress reintroduced an anti-cloning measure on January 8, 2003.<sup>169</sup> The House of Representatives measure is identical to the previous bills H.R. 2505 and S. 1899.<sup>170</sup> The measure did not go to immediate vote and it was referred to the

measures, S. 1758 and S. 1893, included more focus on and protection of stem cell research. *See* S. 1893, 107th Cong. (2002); S. 1758, 107th Cong. (2001); *supra* text accompanying note 164. With the widest Senate support, S. 1899 focused exclusively on the specific prohibition of human cloning. The only mention of possible medical research in S. 1899 was § 302(d) which stated "[n]othing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans." S. 1899, 107th Cong. § 302(d) (2002).

166. *See generally* *Human Cloning: Must We Sacrifice Medical Research in the Name of a Total Ban?: Hearings on S. 1899 Before the Senate Judiciary Comm.*, 107th Cong. (2002), available at <http://judiciary.senate.gov/hearing.cfm?id=147> (last visited Oct. 21, 2003).

167. *See generally* R. W. Apple, Jr., *President's Risks Are Rewarded at Polls*, N.Y. TIMES, Nov. 6, 2002, at A1; Press Release, Council for Responsible Genetics, Momentum Builds in Congress for a Cloning Ban (Jan. 8, 2003), available at <http://www.gene-watch.org/press/cloning-010703.html> (last visited Oct. 21, 2003).

168. White House Press Briefing (Nov. 6, 2002), available at <http://www.whitehouse.gov/news/releases/2002/11/20021106-1.html> (last visited Oct. 20, 2003). In the Briefing, Press Secretary Ari Fleischer stated:

I think there's no question that last night's [election] results increase the likelihood of getting things done for the American people. There are many initiatives that could have and should have been done in the last Congress that got bottled up and stopped that now have a much stronger chance of getting done. Having said that, of course, in the Senate, if members decide that they still want to exercise all their parliamentary rights, they can block, they can filibuster, they can use 60 votes to thwart a growing bipartisan consensus. But let me . . . walk through a list of the things that were left undone from the last Congress that the President still remains very interested in. . . . Some issues got stuck in a House-Senate conference committee . . . . A ban on human cloning was passed by the House and not take[n] up by the Senate. So there remain a wide variety of issues that have not gotten done in this last closely divided Congress.

*Id.*

169. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003).

170. *Compare* S. 1899, 107th Cong. (2002) *and* H.R. 2505, 107th Cong. (2002) *with* H.R. 534, 108th Cong. (2003).

House Judiciary and Energy and Commerce Committees.<sup>171</sup> Despite the delay, the measure was debated and passed during the last week of February 2003.<sup>172</sup> Likewise, the sponsor of the original Senate initiative, Senator Sam Brownback, reintroduced a full cloning ban as S. 245, or the Human Cloning Prohibition Act of 2003, in late January 2003.<sup>173</sup>

### III. ANALYSIS

Despite any impending action in Congress on a reproductive cloning ban in the United States, significant questions still remain about the application of moral utility within the United States patent system. This section will address three major issues that limit moral utility's application: first, the shortsightedness of future moral utility analysis within the courts and the USPTO; second, the USPTO's legitimate concern over continued reliance on the doctrine and the possible conflict with the United States Supreme Court precedent defining patentable subject matter; and third, the principle's inconsistency with the policy goals of the United States patent system.

#### A. Possible Applications of Moral Utility

Although no judicial opinion has dismissed moral utility entirely, its direct application to patentable utility is severely limited. The most glaring difficulty recognized by the courts and the USPTO is that moral utility most readily applies to an invention's use—a property right not conferred by the patent grant.<sup>174</sup> With a federal ban on cloning looming over the legislative horizon, illegality may be one avenue for moral utility's function in modern patent law.

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171. See H.R. 534, *supra* note 169, available at <http://www.congress.gov/cgi-bin/query/z?c108:H.R.534>: (last visited Oct. 21, 2003) (stating that the bill was “referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for such a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned”).

172. See Library of Congress, Bill Summary and Status Information, available at <http://www.congress.gov/cgi-bin/bdquery/z?d108:h.r.00534> (last visited Nov. 2, 2003). “Rule provides for consideration of H.R. 534 with 1 hour of general debate. Previous question shall be considered as ordered without intervening motions except motion to recommit with or without instructions. Measure will be considered read. Specified amendments are in order.”

173. See generally Press Release, Brownback Reaction to Human Cloning Claim (Dec. 27, 2002), available at <http://www.brownback.senate.gov/LICloning.cfm> (last visited Oct. 20, 2003); Human Cloning Prohibition Act of 2003, S. 245, 108th Cong. (2003), available at <http://www.congress.gov/cgi-bin/query/z?c108:S.245> (last visited Oct. 20, 2003).

174. See MERGES & DUFFY, *supra* note 7 (stating “[p]atent rights are wholly negative rights—rights to stop others from using—not positive rights to use the intervention”) (emphasis in original).

1. *The Federal Circuit Limitations on Moral Utility and the Implications of Juicy Whip*

The Federal Circuit refused to uphold the previous evaluation of moral utility in *Juicy Whip* not because the doctrine was useless, but because the lower court's application of the doctrine was flawed. *Juicy Whip* specifically claimed the "simulated beverage display" to increase sales.<sup>175</sup> The district court's conclusion that the invention lacked utility because "it conferr[ed] no benefit to the public other than the opportunity for making a product more salable" was fundamentally flawed because that reasoning included a moral judgment not based upon accepted interpretations of § 101. The lower court made the subjective determination that the public benefit of "making a product more salable" was not enough for patentable utility; that the stated utility was immoral and therefore unpatentable. Furthermore, the cases relied upon by the lower court were not interpretations of utility under the current 1952 Patent Act.

As the Federal Circuit Court of Appeals stated, the lower court's analysis included an impermissible personal evaluation of the invention's moral utility. The earliest cases invalidating gambling device patents did so because of the prevalent statutory and social atmosphere of the time. These early decisions were not made in a judicial vacuum; gambling was considered immoral by most members of society. Almost all states and the federal government included criminal penalties for gambling in various forms, and therefore, any invention in support of those purposes was also immoral and lacked patentable utility.<sup>176</sup> Furthermore, gambling was illegal in almost every jurisdiction in the United States at that time.<sup>177</sup> These decisions survived, in part, because their reasoning was not solely based on the judge's personal morality, but referred to the illegality of the device itself.

In *Juicy Whip*, the Federal Circuit only refused to follow the lower court when it based its evaluation of utility on the deceptive function

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175. See *Juicy Whip v. Orange Bang*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

176. See *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903). In dissent, Judge Grosscup stated:

Gambling and gambling devices are condemned by the laws of every state and territory, except perhaps New Mexico. Upon this it can be safely predicated that the conscience of the people of the state in which this court sits; of the people of the three states that constitute this circuit; indeed, of the people of every state and territory, except a little territory bordering on Mexico, condemns the practice of gambling. Gambling and gambling devices are condemned, also, by the enactments of congress . . . .

Thus the national conscience is seen to be outspoken against this practice. Nothing could be conceived more conclusively showing a general conception of policy.

*Id.* at 279 (Grosscup, J., dissenting).

177. *Id.*

of the simulated beverage display.<sup>178</sup> Deception in the form of a simulated beverage display, the court noted, was not illegal.<sup>179</sup> The court went on to illustrate several valid patents covering inventions designed only to deceive.<sup>180</sup> Furthermore, the court noted that Orange Bang did not argue that it was illegal to display a simulated representation of the beverage.<sup>181</sup> However, if Orange Bang had argued that the invention was illegal, the court stated that administrative agencies existed specifically for protecting "consumers from fraud and deception in the sale of food products."<sup>182</sup> Therefore, the fatal flaw in the lower court's reasoning was not its invocation of moral utility, but its improper application of the doctrine to an invention with a legal function and a lack of deference to specific regulatory agencies governing illegal uses in the sale of food products. After *Juicy Whip*, one narrow application of the moral utility doctrine might exist in a patent covering an invention that could serve no possible legal purpose and in which no regulatory agency had the authority to restrict its use.

## 2. *Possible Application of Whistler Corp. v. Autotronics, Inc. Reasoning*

One district court agreed with the reasoning that a total ban of a particular invention would invalidate a patent for lack of utility.<sup>183</sup> In an infringement action regarding automobile radar detectors, the court reasoned that an outright prohibition of an invention might provide courts with clear and convincing evidence that an invention has no patentable utility.<sup>184</sup> Applying the same reasoning to the case of human cloning, a court might find reasonable grounds for lack of patentable utility from a complete federal ban of the claimed procedure.

Although it does not include a specific exclusion from patentable subject matter for human cloning, the 2003 Human Cloning Prohibition Act may provide an avenue for denying such protection through invalidity actions and reinforce the USPTO's reasoning for rejecting such patents. Identical to the now defunct H.R. 2505, the proposed law merely imposes criminal and civil liability on anyone who clones a

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178. *Juicy Whip*, 185 F.3d at 1366-67.

179. *Id.*

180. *Id.* (noting several well-known patents for deceptive products, such as cubic zirconium, as designed to simulate diamond, U.S. Pat. No. 5,762,968, which covers a method for producing imitation grill marks on food without heat, and U.S. Pat. No. 5,571,545, which covers an imitation hamburger).

181. *Id.*

182. *Id.* at 1368 (citing *In re Watson*, 517 F.2d 465 (C.C.P.A. 1975)).

183. See *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885 (N.D. Tex. 1988).

184. See *id.*

human.<sup>185</sup> Hearings and debate surrounding the old measure focused on its implication for medical research and the issue of patentability garnered little attention.<sup>186</sup> As written, the new measure would provide guidance for the USPTO and courts to further apply moral utility to reject patents directed to human cloning; however, even the enacted law would not be the best guidance. Inclusion of a measure, such as 42 U.S.C. § 2181(a), which specifically excluded nuclear weapons from patentable subject matter, would be the clearest form of guidance for the USPTO and would provide the strongest possible basis for rejection of a patent directed to human cloning.

Applying moral utility in the illegality context would still face significant limitations based on precedent and the function of patents. In *Fuller v. Berger*, the court recognized that the patent does not confer the positive right to use the invention, but only the right to exclude.<sup>187</sup> Significantly, the *Fuller* court recognized that illegality solely concerns the use of an invention, not the grant or denial of the patent, and that a user of an illegal invention is “amenable to the municipal authorities alone for violations of the municipal law.”<sup>188</sup> The concept that the patent confers no positive right to use or possess the invention, but merely the right to exclude, continued after passage of the 1952 Act and subsequent opinions recognize the court’s reluctance to imply lack of patentable utility based on an invention’s use.<sup>189</sup> *Juicy Whip* continued this judicial understanding of utility when it repeated what

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185. See *supra* note 162 and accompanying text.

186. See *supra* note 166 and accompanying text.

187. *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903). The court stated that:

The inventor’s right to make, vend, and use his device does not come from the patent law; it is his natural right. The government’s grant to the patentee and his assigns is the right to exclude others from practicing the invention . . . . “The franchise which the patent consists altogether in the right to exclude every one from making, using, or vending the thing patented, without permission of the patentee. This is all he obtains by the patent.” [A] law which prohibits the use of a certain article, which is patented, is not in derogation of the inventor’s grant under the patent law . . . . [The] law operates wholly upon the inventor’s natural right to the use of his property, and not at all upon the franchise which the patent grants, which consists altogether in the right to exclude.)

*Id.* (quoting Chief Justice Roger B. Taney in *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 548 (1852), and concluding, “It is equally obvious that, however the court may act upon complainant’s asserted right to exclude, neither the grant nor the denial of the writ of injunction would operate on complainant’s practices or habits . . .”).

188. *Id.*

189. See generally *Coll. Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666 (1999) (describing the right to exclude as the “hallmark of a protected property interest”); *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979) (reasoning that the right to exclude was “one of the most essential sticks in the bundle of rights that are commonly characterized as property”); *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988) (concluding that the inventor had no right to use the invention in states that outlaw radar detectors, but that limitation did not affect his patent rights).



the Supreme Court stated in the 1880 decision of *Webber v. Virginia*, that “Congress never intended that the patent laws should displace the police powers of the States . . . .”<sup>190</sup> If it is only the use of the invention that is illegal, then the patent cannot be denied for utility on the basis of that same illegality because the patent merely grants its owner the limited right to exclude.

Conversely, the Federal Circuit’s reliance on *Webber* might not be true to the Supreme Court’s understanding of utility under the 1952 Act. In *Brenner v. Manson*, the Supreme Court emphasized the “benefit derived by the public” in its definition of utility.<sup>191</sup> To be patentable, an invention must have “specific” and “substantial utility” which, by the grant, bestows a “specific benefit” on the public.<sup>192</sup> Following an interpretation of this precedent, the USPTO adopted the 2001 Utility Examination Guidelines which use “specific, substantial, and credible” to define patentable utility.<sup>193</sup> In approving the Guidelines, the USPTO affirmed that patents confer the right to exclude and denied their ability to grant title or ownership.<sup>194</sup> According to the Supreme Court’s reasoning in *Brenner*, the public can derive no benefit from an invention whose purpose is purely and specifically forbidden by law. Under *Brenner*, such an invention might be invalid for lack of utility. Likewise, under the USPTO guidelines, an invention expressly banned by federal law might stumble on the hurdles of “specific, substantial, and credible” utility under the Guidelines.<sup>195</sup>

By defining patentable utility as a benefit to the public, the Supreme Court seems to take into account other courts’ reluctance to invalidate patents for lack of utility based on the illegality of their use. To some degree, the USPTO still uses this reluctance to justify the grant. Based on this narrow interpretation, should Congress enact a full human cloning ban, it is possible that the Federal Circuit or the USPTO would invalidate or reject a patent directed to human cloning based on the illegality aspect of moral utility. However, as illustrated by the well-received *Fuller* reasoning, the inherent connection to the

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190. See *Juicy Whip*, 185 F.3d at 1368 (quoting *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880)); *supra* note 120 and accompanying text.

191. *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

192. *Id.*

193. See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

194. See *supra* note 138.

195. See Utility Examination Guidelines, 66 Fed. Reg. at 1092. Following the “Utility Review Flowchart” provided with the training materials on the website, a banned invention might pass muster for a “specific” utility, but would probably fail under an evaluation of “substantial” utility because an illegal use might be defined as “throw away,” which is specifically noted as a basis for rejection. *Id.*

invention's use implied by a denial based on illegality might be incompatible with established policies of the American patent system.

### B. *The USPTO's Reluctance to Apply Moral Utility*

As an administrative agency, the USPTO implements federal legislation and interprets judicial opinions relating to its function.<sup>196</sup> The USPTO must base any grant or denial on established laws and precedent, or face reversal by a court. The USPTO's frustration and reluctance to apply moral utility to the most controversial aspects of biotechnology illustrates the agency's delicate balancing act between interpretation and administration. Since the first controversial application for a patent directed to human-animal chimeras in 1998, the USPTO has implemented a patchwork policy that refuses inventions it considers "encompassing a human being . . ."<sup>197</sup> By its own admission, the USPTO considers its procedure on tenuous legal grounds.<sup>198</sup> To solidify its ability to continue rejecting human cloning patents, the USPTO has publicly stated its desire for congressional clarification on the issue in the form of legislation excluding the controversial procedure from patentable subject matter.<sup>199</sup> Until Congress enacts a specific exclusion, moral utility will likely continue to be one of the possible bases for rejection of an otherwise valid application directed to human cloning. The USPTO's reliance on moral utility to deny protection for these inventions, whether illegal or not, will likely face sound legal objections in any action brought to challenge such a rejection. Although the USPTO's reluctance to impart moral judgments during the examination process might be diminished with a congress-

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196. See generally MERGES & DUFFY, *supra* note 7, at 1153. Merges and Duffy explain that, "Unlike the other institutions in the patent system, the USPTO is an administrative agency, not a court. [One of the main features of the USPTO is that it] has not only legal, but technical expertise." *Id.*

197. See Hauda, *supra* note 154 and accompanying text. The Manual states that:

It is clear from the Supreme Court decision . . . [of *Diamond v. Chakrabarty*] that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention . . . . [summarizing the relevant points of *Chakrabarty* and concluding:] The Office will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in *Chakrabarty*, e.g., that "a nonnaturally occurring manufacture or composition of matter" is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed . . . . If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

*Id.*

198. See Hauda, *supra* note 154; see also *supra* text accompanying note 160.

199. *Id.*

sional ban on human cloning, a complete solution will result only from the specific exclusion of human cloning from patentable subject matter.

### 1. *USPTO's Consideration of Moral Utility in Rejections of Human Cloning Patents*

The USPTO does not consider moral utility to be the most logical reasoning for rejecting patents directed at human cloning. Although still viable by the Agency's interpretive authority, the USPTO's testimony before the President's Council on Bioethics pointed to glaring logical errors that might be committed if the agency continued to rely on the doctrine.<sup>200</sup> Acknowledging a combination of three factors that the office used to reject patents directed to human cloning, a Supervisory Patent Examiner stated that "the courts have interpreted the utility requirement to exclude inventions deemed to be injurious to the well-being, good public policy, or good morals of society."<sup>201</sup> Considering the notable absence of congressional guidance excluding human clones from patentable subject matter under the Human Cloning Prohibition Act of 2003, the USPTO's reluctant recognition of the doctrine, even in the narrow exception left after *Juicy Whip*, points to the possibility of continued, albeit misplaced, application.

Analysis of the specific factors the USPTO uses to reject patents directed at human cloning reveals that the agency's reasoning runs afoul of Supreme Court precedent. The USPTO has specifically stated that, regarding the application of utility to human cloning, the Office will reject such applications based on three factors: first, the language of § 101 does not include humans as patentable subject matter; second, conferring rights over humans may raise constitutional questions; and third, courts have interpreted § 101 as excluding inventions based on moral grounds.<sup>202</sup> The USPTO qualified the last factor in light of *Juicy Whip* and concluded that grounds for rejection based on morality are tenuous.<sup>203</sup>

The first factor that considers the subject matter limitations of § 101 conflicts with Supreme Court precedent. In *Chakrabarty*, the Court interpreted the meaning of the patentable subject matter provisions of § 101.<sup>204</sup> Under the 1952 Patent Act, § 101 described patentable subject matter as a "process, machine, manufacture, or composition of

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200. See Rai, *supra* note 157 and accompanying text.

201. *Id.*

202. See *supra* notes 156-158 and accompanying text.

203. See Hauda, *supra* note 154; Rai, *supra* note 157.

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

matter, or any new and useful improvement thereof.”<sup>205</sup> Upholding a patent directed to an organism created through genetic manipulation, the Court stated that § 101 was an embodiment of the statute’s legislative history that broadly defined protection for “anything under the sun that is made by man.”<sup>206</sup> Furthermore, the Court concluded that, as a product of human ingenuity, the modified organism in *Chakrabarty* was not precluded by the broad language of § 101.<sup>207</sup>

By analogy, human clones are the result of genetic manipulation and are necessarily man-made. With respect to patents claiming the products of human cloning, the USPTO stated that the language of § 101 could not include this subject.<sup>208</sup> Following the reasoning of *Chakrabarty*, which defined patentable subject matter as “anything under the sun that is made by man,” it is logical to conclude that either the Supreme Court or the Federal Circuit would overrule a USPTO rejection of a human cloning patent if it were based on the Agency’s misguided formulation of patentable subject matter. The USPTO’s reliance on any perceived limitations in § 101 is likely misplaced and could possibly be overruled in the federal courts.

Similarly, the USPTO’s statements in response to inquiries concerning the limits of patents granted to the University of Missouri signal that the Agency’s policy regarding patents on human cloning is inconsistent with *Chakrabarty*. Concerned that the patent claiming techniques and products from genetically modified pigs for use as human organ donors amounted to human cloning, several media sources pressed the USPTO for comment about the extent of the grant.<sup>209</sup> In response, the USPTO stated that it would not grant patents on humans “because it had not received any guidance from Congress or the courts saying it should do so.”<sup>210</sup> The Supreme Court rejected similar USPTO reasoning that, until Congress expressly authorized patent protection for living organisms, the Office could not expand patentable subject matter to include the genetically-modified organism at issue.<sup>211</sup> In *Chakrabarty*, the USPTO refused a patent on a living organism in part because Congress had not specifically included protection for living things and the Office should not so greatly expand patentable subject matter without firm guidance.<sup>212</sup> Relying on

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205. *Id.* at 307.

206. *Id.* at 309.

207. *Id.*

208. See *supra* note 154 and accompanying text.

209. See *supra* note 149 and accompanying text.

210. See *supra* note 152 and accompanying text.

211. See *Chakrabarty*, 447 U.S. at 303; see also *supra* note 91 and accompanying text.

212. See *Chakrabarty*, 447 U.S. at 303; see also *supra* text accompanying notes 87-88.

the legislative history of § 101, the Court rejected the USPTO's reasoning and concluded that "[b]road general language is not necessarily ambiguous when congressional objectives require broad terms."<sup>213</sup> By the Court's interpretation of the Patent Act, all endeavors of human invention are necessarily patentable subject matter.<sup>214</sup> Therefore, it is likely that relevant Supreme Court precedent does not support the USPTO's current justification for rejecting human cloning patents based on a lack of congressional guidance. Rejections based on this justification are likely to fail, as in *Chakrabarty*.

Regardless of the response to inquiries concerning the University of Missouri patent, it is important to understand why the grant likely does not encompass a human being. Two considerations bring serious doubt to allegations that the patent issued to the University of Missouri actually claimed human cloning. First, the USPTO has specifically refused to issue patents claiming human cloning.<sup>215</sup> The guidance presented by the USPTO in testimony before the President's Council on Bioethics outlined the specific steps the examiners take when considering potential human cloning patents.<sup>216</sup> Based in part on the moral utility doctrine, the USPTO's official conclusion is that human cloning is not patentable and that the Agency has the interpretive authority to make this decision absent specific guidance from Congress.<sup>217</sup> The USPTO's examination process and the fact that the USPTO refuses to issue patents directed to human cloning provides credible authority that the University of Missouri patent does not actually claim the process or its products.

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213. *Chakrabarty*, 447 U.S. at 315; see also *supra* text accompanying note 90.

214. See *supra* notes 89-91 and accompanying text. *Id.* at 309. *Chakrabarty* explained the parameters of § 101:

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

*Id.*

215. See *supra* notes 154-160 and accompanying text.

216. See *supra* notes 154-160 and accompanying text.

217. See *supra* notes 154-160 and accompanying text. Hauda stated:

[O]n June 11th, 1987 the USPTO's Assistant Commissioner testified that a claim, including a human being within its scope, will not be considered to be patentable subject matter. In the 15 years since it was notified of the USPTO's interpretations, Congress has apparently acquiesced to the USPTO interpretation. Further, the Federal Circuit held in 1991 that the USPTO has the authority to establish its policy through interpretive authority.

Hauda, *supra* note 154.

Second, the examination and prosecution process is only intended to give a “rough, first cut” answer to the question of validity.<sup>218</sup> After successful prosecution, a patent is only “presumed valid” and the courts make the final determination of validity and of the breadth of the claims in subsequent infringement actions.<sup>219</sup> Therefore, even if the University of Missouri patent actually claims human cloning, the validity of that claim is unclear without a subsequent judicial determination. Based on the express USPTO policy against human cloning and the mere presumption of validity created by issuance, the contention that the University of Missouri patent actually claims human cloning is questionable.<sup>220</sup>

Concerning the general application of the USPTO factors, as testimony before the President’s Council on Bioethics illustrated, the Agency will reject an application on a combination of factors and not solely on the basis of improper subject matter. To the extent that *Juicy Whip* weakened the USPTO’s ability to consider moral utility as one of the factors, the Office is not comfortable with maintaining a rejection on this basis.<sup>221</sup> The USPTO acknowledged the implication of the Federal Circuit’s questioning the viability of moral utility in *Juicy Whip* that, should the Agency’s current policy toward human cloning patents come before the court, “the resulting outcome, especially on public policy grounds, . . . [would be] . . . uncertain.”<sup>222</sup> While a federal ban on human cloning might bolster the USPTO’s ability to apply moral utility to rejections on patents directed to that process, such a prohibition is far from the clear patentable subject matter guidance the Agency desires.<sup>223</sup>

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218. MERGES & DUFFY, *supra* note 7, at 1154; *see also supra* text accompanying note 7.

219. 35 U.S.C. § 282 (2002) (“Presumption of validity; defenses: A patent shall be presumed valid.”).

220. *See supra* notes 154-160 and accompanying text. One future policy question is whether the USPTO’s responsibilities should be expanded beyond their traditional examination scope. The agency has limited itself to only revising defective patent though correction and reissue. With passage of 35 U.S.C §§ 301-307 in 1980, Congress sought to “strengthen. . . the certainty of patent rights by establishing a system of administrative reexamination of doubtful patents.” *See* H.R. REP. NO. 96-1307 (1980), *reprinted in* 1980 U.S.C.C.A.N 6460, 6462. In 1999, Congress passed 35 U.S.C §§ 311-318, which allowed potential infringers the ability to challenge a patent’s validity through reexamination. This shift might signal an expansion of the USPTO’s role, possibly to the eventual conclusion that the agency decides all challenges to validity. For a brief examination of this possibility, *see also* MERGES & DUFFY, *supra* note 7, at 1154.

221. *See supra* note 220 and accompanying text.

222. *See* Hauda, *supra* note 154.

223. *Id.*

C. *Moral Utility as Inconsistent with the Goals of the United States Patent System*

Moral utility cannot stand in harmony with the broad goals of the United States patent system, whether based on objective considerations of legislative opinion through illegality or on entirely subjective opinions of judges and patent examiners. As stated in the Constitution, the patent system exists “[t]o promote the Progress of Science and the useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”<sup>224</sup> It was Jefferson’s belief that “ingenuity should receive a liberal encouragement” that drove America’s industrial creativity and progress.<sup>225</sup> By granting the right for a limited time to exclude others from practicing an invention, the patent provides an important incentive for the inventor and potential investors to find, support, and exploit innovative technology. Furthermore, the patent system ensures that other inventors and researchers are aware of the latest technological advances in any given field. Registration encourages the dissemination of important information to provide a solid foundation for further advances or a point to begin new research. Basing an invention’s legal protection on societal considerations of morality or legislative determinations of the legality of its use strips from the scientific community any incentive to find legal or beneficial uses while at the same time decreasing our possible understanding of an entire field of innovation.

Precedent concerning the “injurious” prong of the common definition of moral utility illustrates the benefit of allowing patents directed to human cloning.<sup>226</sup> *In re Anthony* and *In re Watson* concerned appeals from USPTO rejections based on lack of utility. The examiner found no utility in two FDA-approved pharmaceutical compounds that, when applied to humans, had the potential for deadly side effects.<sup>227</sup> In reversing the USPTO rejection, the court stated that safety was not a component of patentable utility.<sup>228</sup> Federal agencies, the court noted, were the proper arbiters of an invention’s safety and the USPTO must concede to those offices any well-meaning intentions to protect the public.<sup>229</sup> Most importantly, the court stated that the inventions would be more useful if they were not dangerous, “but the

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224. U.S. CONST. art. I, § 8, cl. 8; *supra* note 25.

225. See 5 WRITINGS OF THOMAS JEFFERSON, *supra* note 27 and accompanying text.

226. See *In re Anthony*, 414 F.2d 1383 (C.C.P.A. 1969); *In re Watson*, 517 F.2d 465 (C.C.P.A. 1975).

227. See cases cited *supra* note 226.

228. *Id.*

229. *Id.*

fact remains that they *are* useful, useful to doctors, veterinarians and research workers, useful to patients . . . and so are useful within the meaning of 35 U.S.C § 101.”<sup>230</sup>

The process of human cloning, at the current stage of research, is undoubtedly dangerous. Nearly all credible authorities in the biotechnology industry recognize that the procedures involved in human cloning entail great risks.<sup>231</sup> However, the patent system does not exist to shield the public from injurious inventions. As stated in *Anthony and Watson*, public safety concerns are specifically reserved for other federal agencies.<sup>232</sup> In support of the broadest policy goals of the patent system, to provide incentives for research and innovation, and to disseminate the most credible technical information possible, even dangerous inventions are patentable.<sup>233</sup> Like the pharmaceutical compounds at issue in *Watson and Anthony*, patents claiming human cloning may be useful to biotechnology scientists and researchers seeking to advance knowledge and understanding in their field. Human cloning patents, because they support the purposes of encouraging innovation and the advancement of knowledge, cannot be denied due to lack of moral utility.

However, because human cloning may have serious effects on public health or other detrimental consequences, allowing such patents may not promote the broad goals of the patent system. Because of the extreme dangers made possible by the unfettered exploration of this technology, rejection of patents claiming human cloning might be the best solution. Nuclear weapons, for example, were so dangerous to society that Congress denied all patent protection for such inventions.<sup>234</sup> Private innovation in the field of nuclear weapons is not something that the patent system should encourage, and neither should information regarding such innovations be widely available

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230. *Id.*

231. Leon R. Kass, *How One Clone Leads to Another*, N.Y. TIMES, Jan. 24, 2003, at A23. Kass stated:

It is true that cloning research offers hope, however speculative, for understanding and treating disease. Yet we should not deceive ourselves about the value and necessity of such research: there is virtually no precedent in animal work that demonstrates the unique benefits of creating and exploiting cloned embryos; we have only just begun to understand existing embryonic stem cells; and promising results with adult stem cells, if confirmed, may obviate altogether the putative need for cloned stem cells . . . .

*Id.* The author is a fellow at the American Enterprise Institute and chairman of the President's Council on Bioethics.

232. See *Anthony*, 414 F.2d 1383; *Watson*, 517 F.2d 465; see also *supra* note 81 and accompanying text.

233. See cases cited *supra* note 232.

234. See 42 U.S.C. § 2181(a) (2000); see also *supra* notes 96, 122 and accompanying text.



due to obvious public safety considerations. Human cloning, with its attendant risks, might be similarly harmful to the public health and safety. Therefore, human cloning patents, like those for nuclear weapons, should be denied protection.

The exclusion of protection for nuclear weapons, however, does not originate from any public safety concerns of the USPTO. The ban on these patents comes from a congressional mandate which specifically narrowed the scope of patentable subject matter.<sup>235</sup> Current legislation to make human cloning illegal does not include a measure similar to 42 U.S.C. § 2181(a) which denied patent protection for nuclear weapons.<sup>236</sup> Similarly, the USPTO recognized that the surest technique to remove human cloning from patent protection would be to include a measure like § 2181(a) in any temporary or permanent ban on human cloning.<sup>237</sup> That no proposed legislation to ban human cloning includes this exclusion from patentable subject matter signals that Congress intends to strike a balance between denying the ability to produce a human clone and promoting the policies of the patent system by allowing such grants to issue. While a ban on human cloning would undoubtedly stifle the methods cloning researchers could employ, ensuring patent protection would promote the exploration of legal methods and guarantee that credible information continued to be available to find legitimate innovation in this field.

It is important to note that all versions of the proposed human cloning ban include provisions for a Government Accounting Office study to be conducted after the prohibition becomes law to assess the prohibition's effects.<sup>238</sup> Likewise, the final recommendations by the President's Council on Bioethics did not call for a complete ban on the

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235. See *supra* note 234.

236. See Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003); S. 245, 108th Cong. (2003); *supra* note 172 and accompanying text.

237. See *supra* note 154 and accompanying text.

238. See Human Cloning Prohibition Act of 2003, H.R. 534. The Act states:

The General Accounting Office after consultation with the National Academy of Sciences shall conduct a study to assess the need (if any) for amendment of the prohibition on human cloning . . . which study should include: 1) a discussion of new developments in medical technology concerning human cloning and somatic cell nuclear transfer, the need (if any) for somatic cell nuclear transfer to produce medical advances, current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer, and potential legal implications of research in somatic cell nuclear transfer; and 2) a review of any technological developments that may require that technical changes be made to . . . this Act.

*Id.*; see also *supra* note 169 and accompanying text.

procedure, but rather, a moratorium.<sup>239</sup> Although both the legislative and executive branches understand the risks of the procedure, they recognize the potential benefits it might produce under a monitored regime. Granting patents to inventors exploring legal and ethical applications of human cloning even under a federal ban of the procedure, would “promote the Progress of Science and the useful Arts” and minimize the moral considerations of this technology.<sup>240</sup>

#### IV. IMPACT

The USPTO will likely continue to apply moral utility to deny human cloning patents. However, rejections based on moral utility will face significant challenges in the federal courts and the USPTO may be forced to abandon its current procedure. The *Juicy Whip* decision seemed to close all but one door on the application of moral utility in patent law. Given the Federal Circuit’s reluctance to freely recognize moral utility and the Supreme Court’s broad understanding of utility and patentable subject matter, it is doubtful that any rejection based on the doctrine could survive judicial scrutiny. Although it remains to be seen how a higher court might view such a rejection should the human cloning ban become federal law, such a determination seems misaligned with the patent system’s incentive and dissemination of information goals. Despite the current presence of the doctrine during the USPTO examination process, moral utility, as illustrated by the Federal Circuit in *Juicy Whip*, seems ill-suited to a system that depends on certainty and objectivity. The practice of rejecting a patent based on personal or societal determinations of morality, at least as applied to mechanical inventions, was abandoned long ago and such abandonment will continue in light of *Juicy Whip*.<sup>241</sup> Allowing moral utility only in the context of an invention’s

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239. PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (2002), available at <http://www.bioethics.gov/reports/cloningreport/index.html> (last visited Oct. 20, 2003). The report stated that

[a] moratorium, rather than a lasting ban, signals a high regard for the value of biomedical research and an enduring concern for patients and families whose suffering such research may help alleviate . . . [A moratorium] would reaffirm the principle that science can progress while upholding the community’s moral norms.

*Id.*

240. U.S. CONST. art. I, § 8, cl. 8.

241. See *Brenner v. Manson*, 383 U.S. 519 (1966) (explaining patentable utility under the 1952 Patent Act as those inventions having “specific” and “substantial utility” which, by the patent grant, bestow a “specific benefit” on the public); *Fuller v. Berger*, 120 F. 274 (7th Cir. 1903) (reversing a lower court’s determination that a patent directed to a device with both legal and illegal uses was invalid); *Juicy Whip v. Orange Bang*, 185 F.3d 1364 (Fed. Cir. 1999) (limiting the application of moral utility as applied to mechanical devices). *Ex parte* Murphy, 200 U.S.P.Q.

illegality still presents significant issues, even though such a rejection would arguably be based on objective factors.

To fulfill the constitutional mandate to promote the progress of science, Congress directs the USPTO to grant patents satisfying a limited set of requirements, among them, that the invention be useful. The rules developed by the USPTO to evaluate applications based on its limited interpretive capacity under the Patent Act and judicial precedent must be based on objective factors. To allow courts and the USPTO to apply subjective ideas of morality will undoubtedly increase uncertainty in application of patent law and stifle innovation and progress in the field of genetic research.

Allowing moral utility to continue as a requirement for patentability may increase uncertainty within the patent system. The narrow exception not yet addressed by the Federal Circuit that possibly remains after *Juicy Whip* would reject or invalidate a patent on the basis of moral utility in the illegality context. Forcing courts to evaluate an invention's patentability based on the legality or illegality of its use would inject a hurdle to protection seemingly without basis in the Patent Act. Requiring an evaluation of the invention's legality would increase uncertainty first, because courts are not equipped to decide issues of patentability from within the context of legislation that originates in the criminal code and second, because an invention may have many uses, legal or not, that the inventor never envisioned.

A court facing an appeal of a rejection based on moral utility's illegality prong would be forced to evaluate patentability based on an act prohibited by the criminal code that may or may not be facilitated by the information contained in the application. The court would have to evaluate the invention's utility based on the likelihood that it would be used to commit a criminal act. Clearly, courts are well-equipped to evaluate the legality of human actions against legislation that criminalizes acts. However, a court evaluating patentable utility by its understanding of an act prohibited under the criminal code would be forced to do so prospectively. The mere fact that the inventor submitted an application for patent protection does not mean that a criminal act has been committed. Although a human cloning patent may claim a process that facilitates a prohibited act, and under a cloning ban no one could practice the specific invention, any determination that the invention lacks utility would be made from the court's understanding that the only use for the claimed invention would be illegal. To gain

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(BNA) 801 (Pat. & Trademark Off. Bd. App. 1977) (declaring gambling devices to be ineligible for analysis under subjective determinations of morality).

this understanding, the court would necessarily have to make subjective determinations concerning the invention's utility based on objective factors derived from a criminal statute. Basing patentable utility on standards bearing no relation or reference to the Patent Act would reduce judicial reasoning to the same level observed in early cases rejecting gambling devices.<sup>242</sup> Subjective determinations based on an invention's possible illegal use would leave inventors with little notice of their discovery's validity.

Furthermore, continued application of moral utility to deny patents directed to human cloning will paralyze certain aspects of the United States biotechnology industry. Although not considered credible or even possible given the field's current state of knowledge, some scientists have predicted that an absolutely perfect process might cure infertility as well as other maladies with a basis in genetics.<sup>243</sup> By removing the ability to protect innovation in this field based on the tenuous application of a legal antique, the USPTO or the courts will do little justice to a system that is the basis for the United States' strength in numerous industrial endeavors. Growth in any technological field requires patents. Moral utility's application to human cloning will only subdue or eradicate the hope of worthwhile advances in this field.

## V. CONCLUSION

Monsters should not be roaming the halls of the USPTO or the federal courts. The simple charge to "promote the Progress of Science and useful Arts . . ." should not be sacrificed for the imposition of subjective moral determinations or on the basis of laws originating in the criminal code.<sup>244</sup> The idea that to maintain the United States' growth in biotechnology, the patent system should support Jefferson's philosophy that "ingenuity should receive liberal encouragement" even if that innovation has the potential to harm, seems repugnant to some members of society, or is actually illegal.<sup>245</sup> Moral utility's slight justification in the wake of *Juicy Whip* seems to be a potential basis for the doctrine's future use, but any further application would be reckless and unsound.

Should the Human Cloning Prohibition Act of 2003 become law, the USPTO and the courts would seem to have an objective basis for moral utility's fresh application. However, the prohibition identified

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242. See, e.g., *Schultze v. Holtz*, 82 F. 448 (C.C.N.D. Cal. 1897).

243. See Kass, *supra* note 231.

244. U.S. CONST. art. I, § 8, cl. 8.

245. 5 WRITINGS OF THOMAS JEFFERSON, *supra* note 27, at 76.

in the proposed law concerns actions having no relevance to the patent system. The proscription of acts central to any criminal code cannot be applied in the context of patentable utility because the patent does not confer any positive right to use or possess the invention claimed. The user of an illegal invention is "amenable to the municipal authorities alone for violations of the municipal law" and the Patent Act cannot further or enforce criminal provisions.<sup>246</sup>

Likewise, current USPTO procedures employing moral utility in the context of human cloning should be abandoned in favor of either Congress's specific removal of the procedure from patentable subject matter or a revision of the agency's examination methods. By relying on moral utility as one of the factors for rejecting these patents, the USPTO continues to make subjective determinations of morality no different than the unfounded rejections of gambling patents at the beginning of the twentieth century.<sup>247</sup> Furthermore, basing rejections on the absence of congressional guidance concerning genetically-modified humans as patentable subject matter runs afoul of direct Supreme Court precedent. The USPTO cannot continue to reject human cloning patents based on its current policy without facing almost certain derision in the federal courts.

The patent system exists to protect ideas, not people. Likewise, the system serves the progress of science and the encouragement of innovation, not the criminal code. Moral utility promotes a vision of the patent as a comprehensive property right and not the limited right to exclude, recognized by almost all interpretations of the Patent Act. Continued recognition of the doctrine will only stifle the quest for knowledge and understanding of human cloning and limit innovation in a burgeoning area of technology. Admittedly, the current understanding of human cloning could wreak havoc on genetic diversity and cause incomprehensible damage.<sup>248</sup> However, the technology could also reveal considerable benefits.<sup>249</sup> Whatever the potential for the

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246. See *Fuller*, 120 F. at 274.

247. See, e.g., *Schultze*, 82 F. at 449.

248. Sheryl Gay Stolberg, *House Votes to Ban All Human Cloning*, N.Y. TIMES, Feb. 28, 2003, at A22. During debate before passage of H.R. 534, the author of the bill, Representative Dan Weldon

held up a white loose-leaf binder on the House floor, saying he had reviewed 88 medical studies and could not find a single one showing cloning's potential. "We're talking about scientists" creating human embryos for the purpose of exploiting them and destroying them . . . [t]here is no scientific evidence today that this is justifiable.

*Id.*

249. *Id.* Stolberg stated:

The National Academy of Sciences has concluded that cloning does hold scientific promise, and 40 Nobel laureates have expressed support for the work. If there is a

technology, rejecting these patents based on moral utility could only serve as an economic disincentive and suppress the spread of credible knowledge. The real danger will not come from publishing these ideas or providing incentives for further exploration, but from suppressing or ignoring them. If the patent system truly exists to promote the progress of science, then it must exorcise this monster called moral utility.

*Andrew R. Smith\**

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dearth of scientific evidence, proponents of [cloning] research say, it is only because cloning is in its infancy, and because there is such political controversy around it that most researchers are loath to try the experiments. "Extreme conviction seems to be crowding out understanding here today," said Representative Rush D. Holt, a New Jersey Democrat who has a Ph.D in physics. "These researchers are not crazed Dr. Frankensteins. They are people like your neighbors, highly ethical, who are working hard to relieve suffering, to improve quality of life. Let's not make them criminals."

*Id.* (referring to NAT'L ACAD. OF SCIENCES, COMM. ON SCI., ENG'G, AND PUB. POL'Y, BD. OF LIFE SCIENCES, SCIENTIFIC AND MEDICAL ASPECTS OF HUMAN REPRODUCTIVE CLONING (2002), available at <http://www.nap.edu/books/0309076374/html> (last visited Nov. 2, 2003); Statement by 40 Nobel Laureates Regarding Cloning, The American Society for Cell Biology available at <http://www.ascb.org/publicpolicy/Nobelletter.html> (last visited Nov. 2, 2003).

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